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(54) **SURGICAL IMPLANT DEVICES AND METHODS FOR THEIR MANUFACTURE AND USE**

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(58) **Field of Classification Search**
None
See application file for complete search history.

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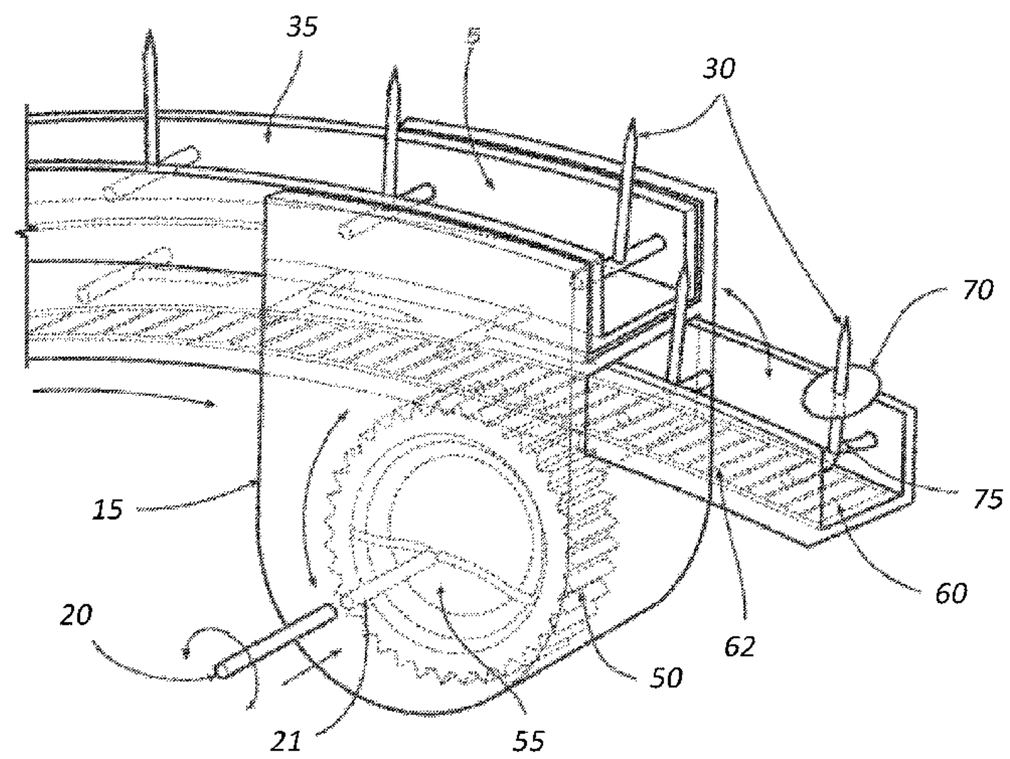
(57) **ABSTRACT**

A vascular system includes a delivery apparatus and an endovascular device. The delivery apparatus including a catheter and a control lead. The control lead extends through a lumen of the catheter and is configured to be manipulated by a user. The endovascular device is releasably coupled to the delivery apparatus and includes an implant body, a seal extending radially outwardly from the implant body, and one or more tissue engaging elements. The seal is configured to contact native vascular tissue to reduce leakage between the native vascular tissue and the implant body. The tissue engaging elements are pivotable relative to the seal from a compressed state to an expanded state. In the compressed state, the tissue engaging elements are positioned so as to disengage the native vascular tissue. In the expanded state, the tissue engaging elements extend outwardly from the seal and are configured to engage the native vascular tissue.

8 Claims, 17 Drawing Sheets



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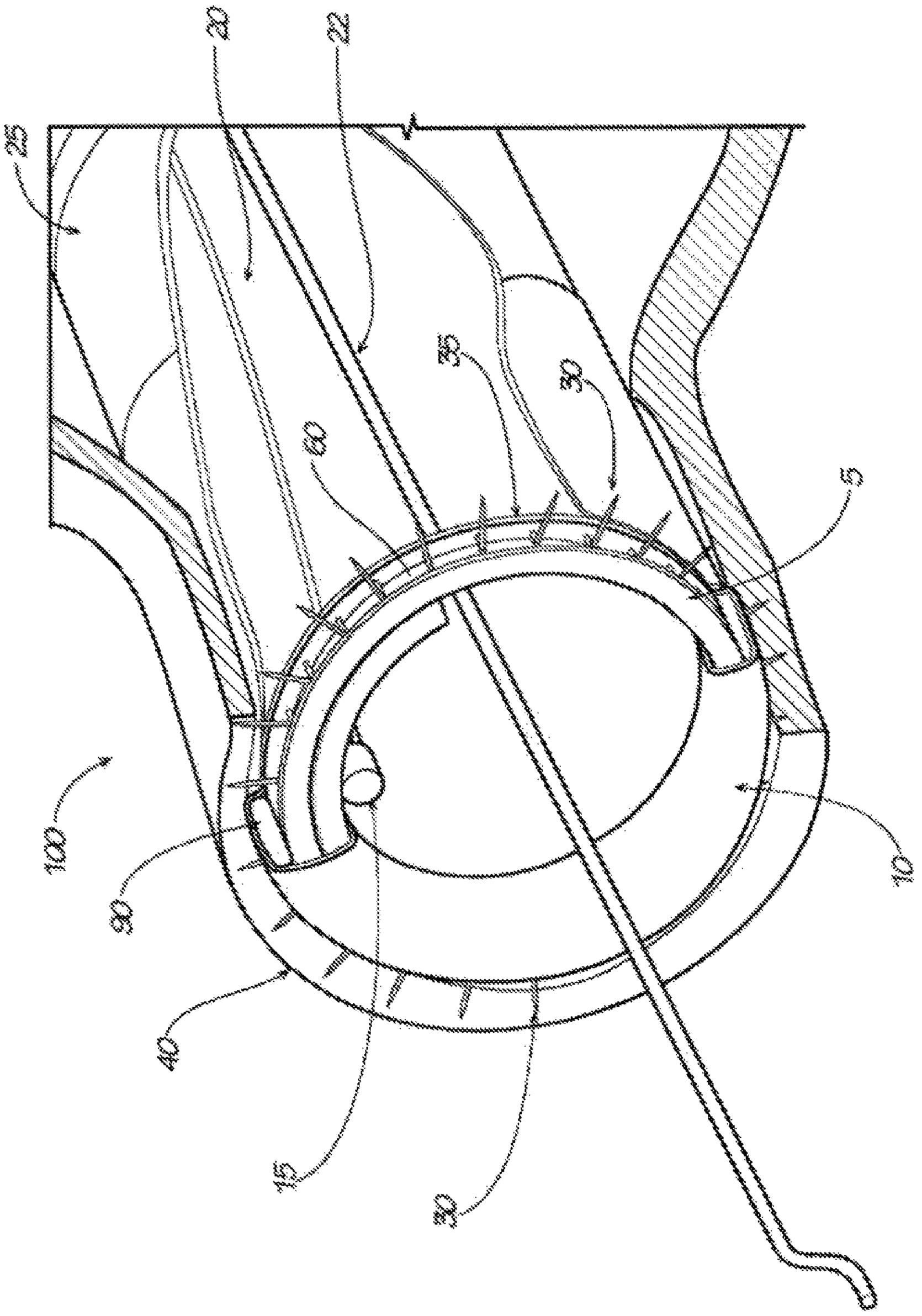


FIG. 1A

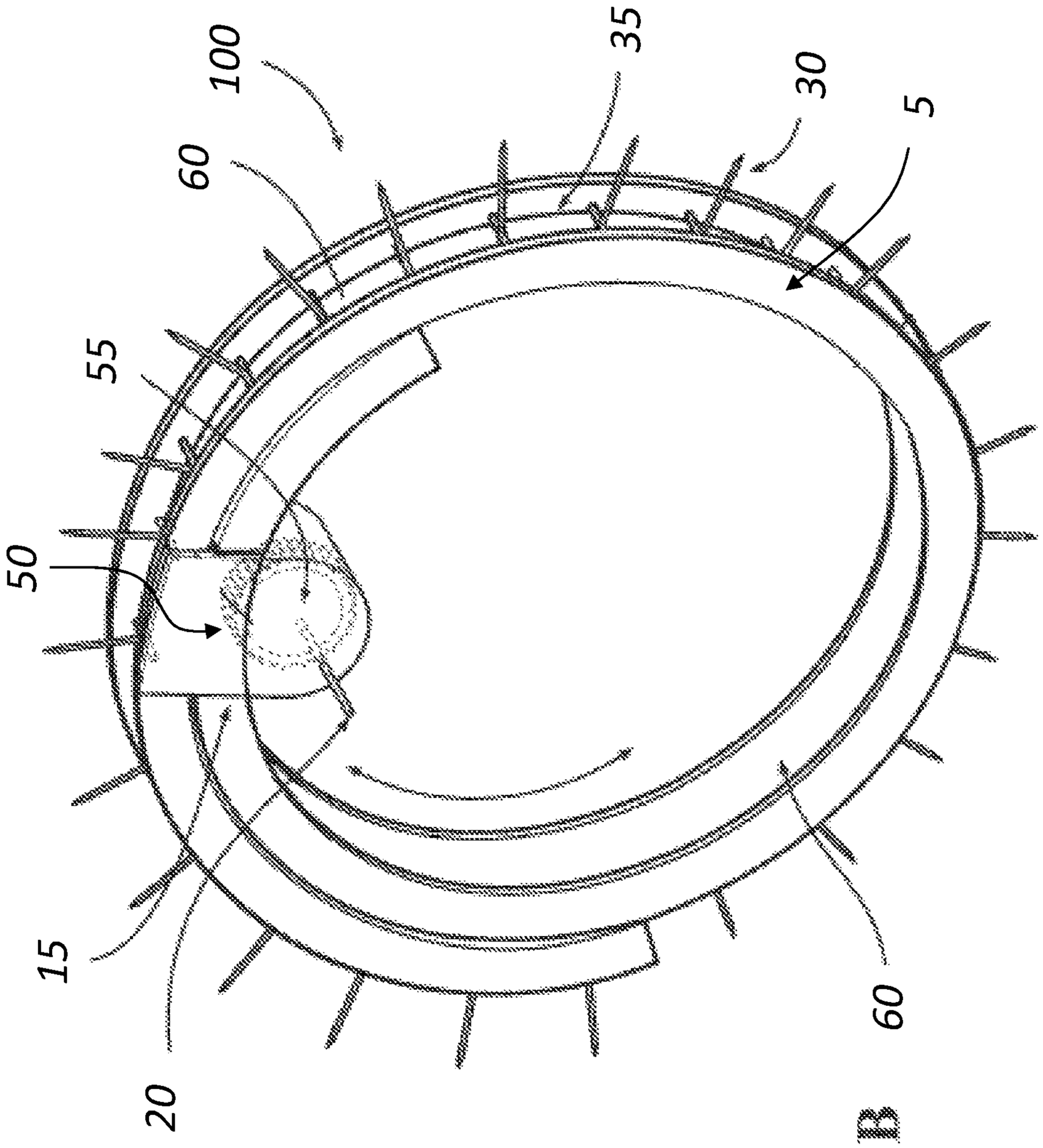


FIG. 1B

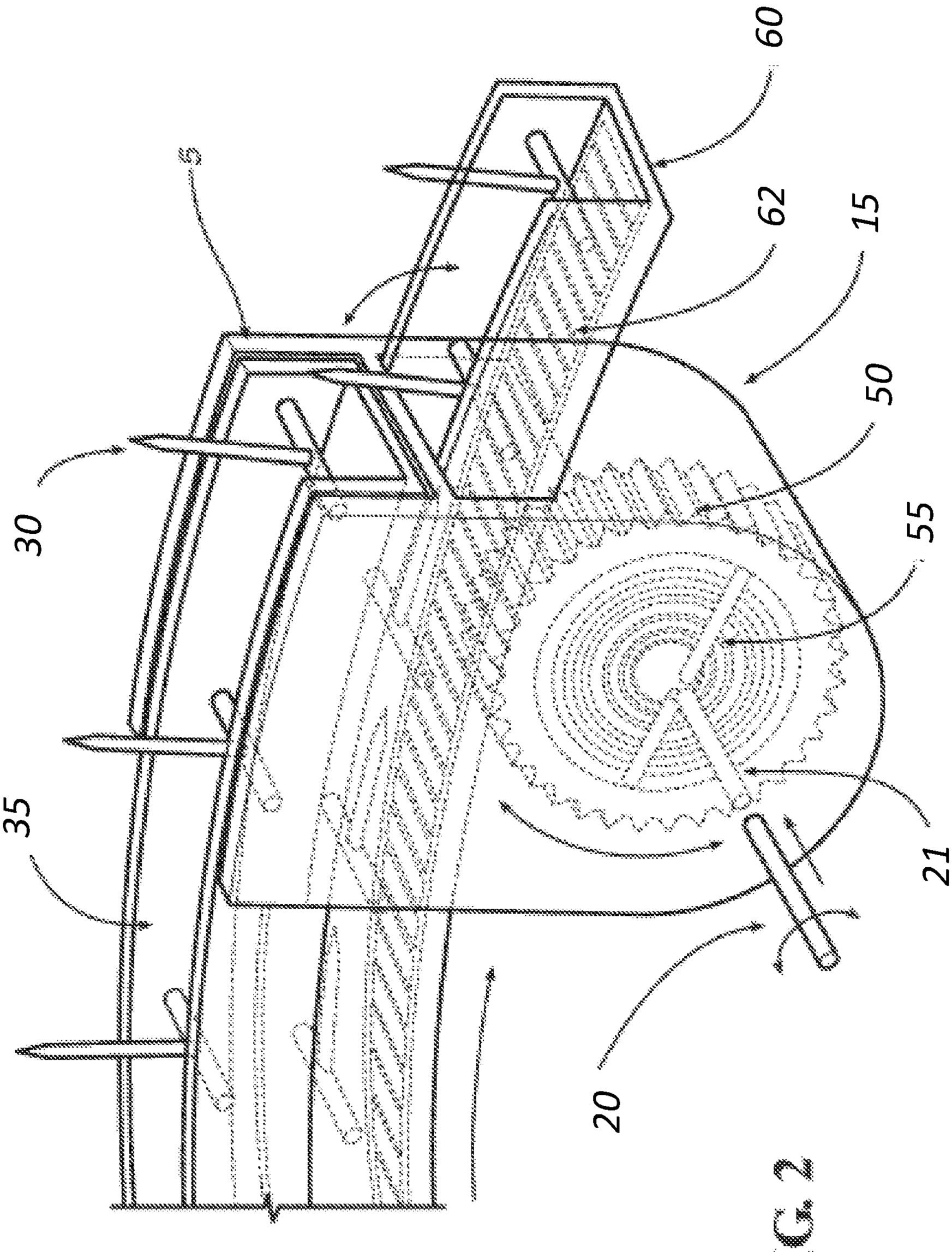


FIG. 2

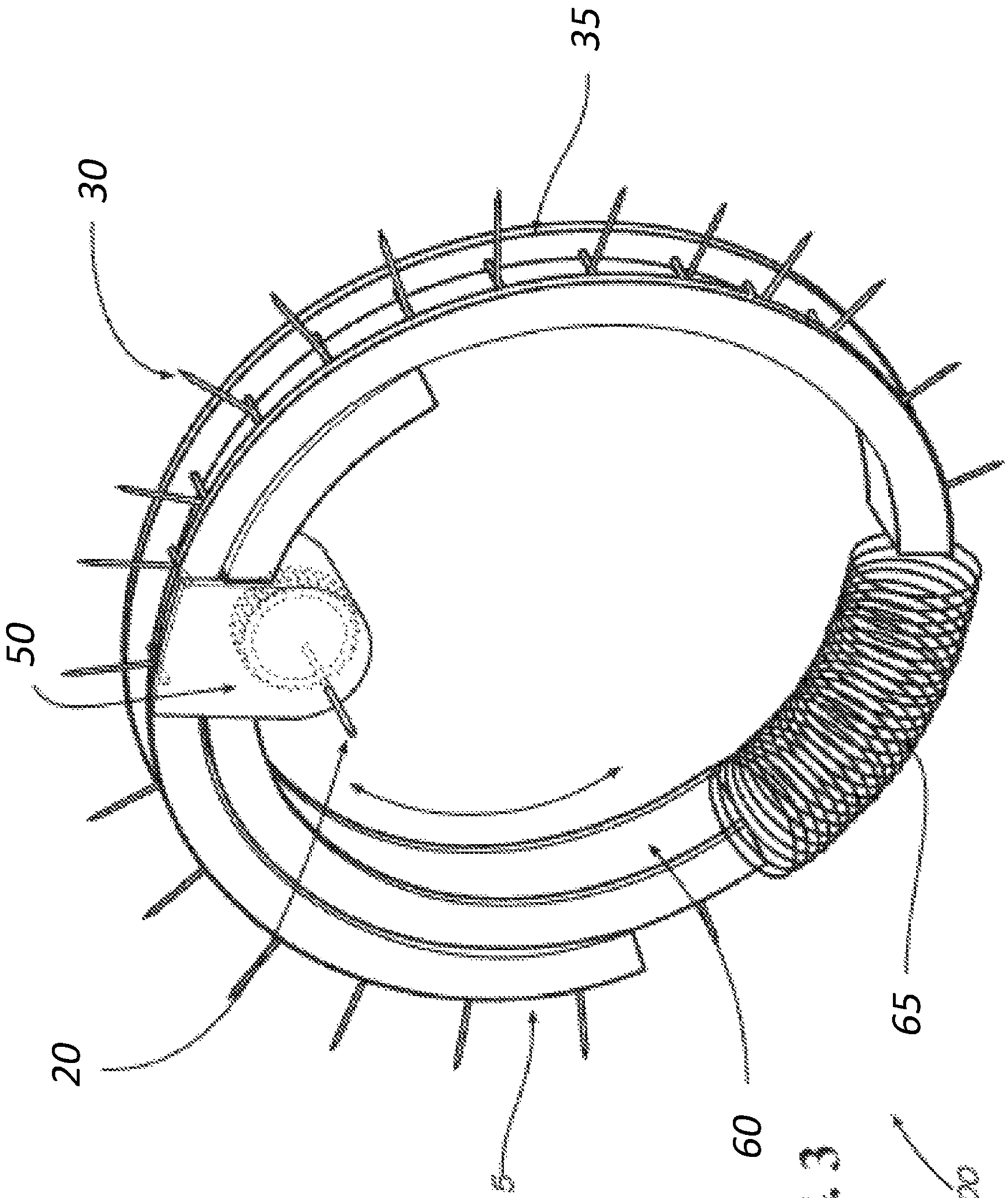


FIG. 3

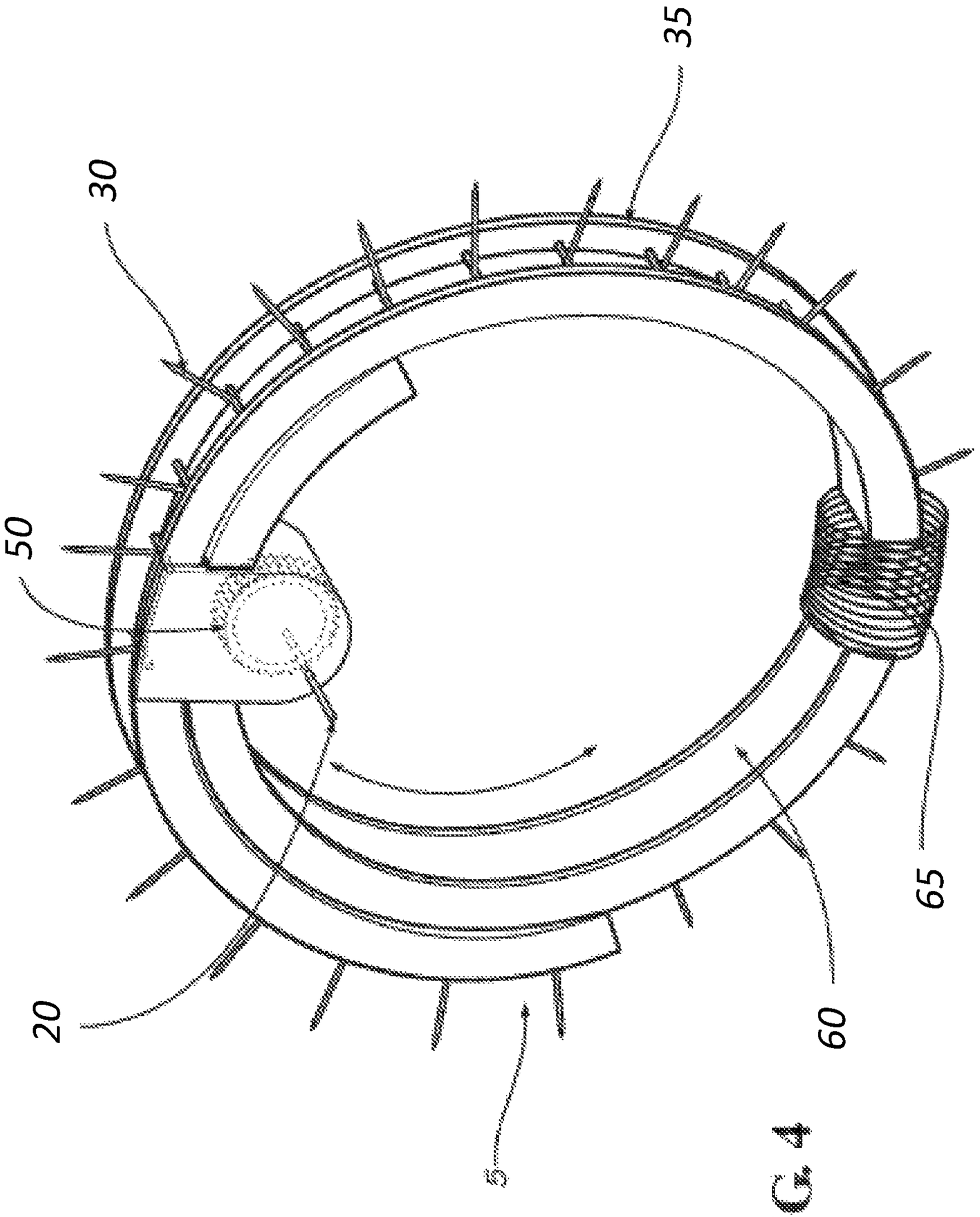


FIG. 4

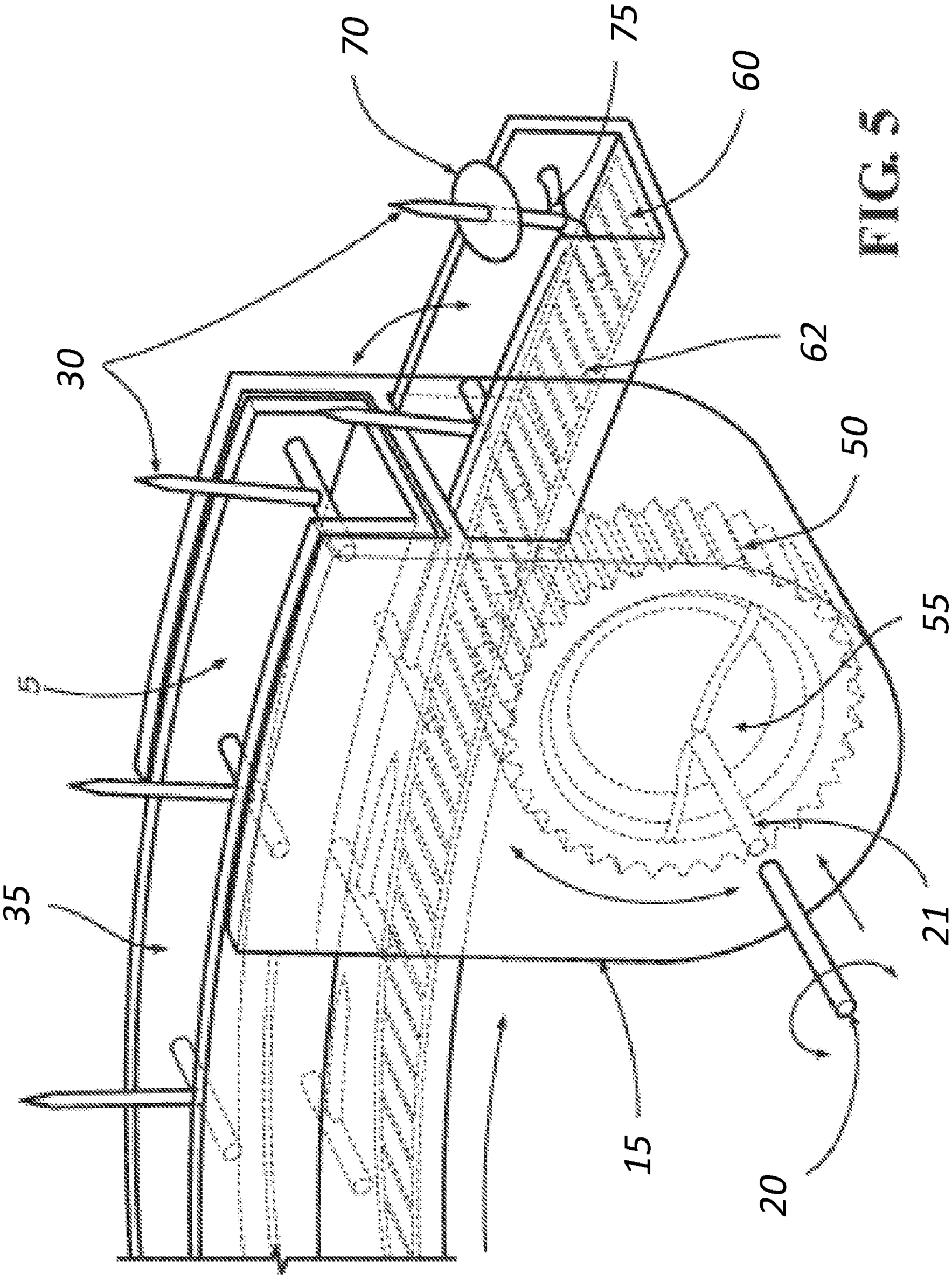


FIG. 5

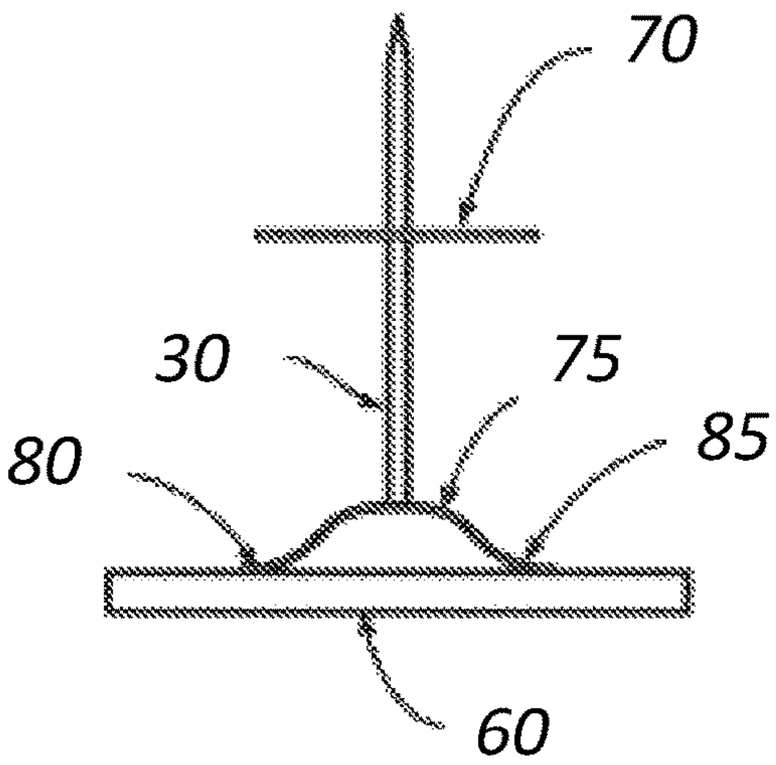


FIG. 6A

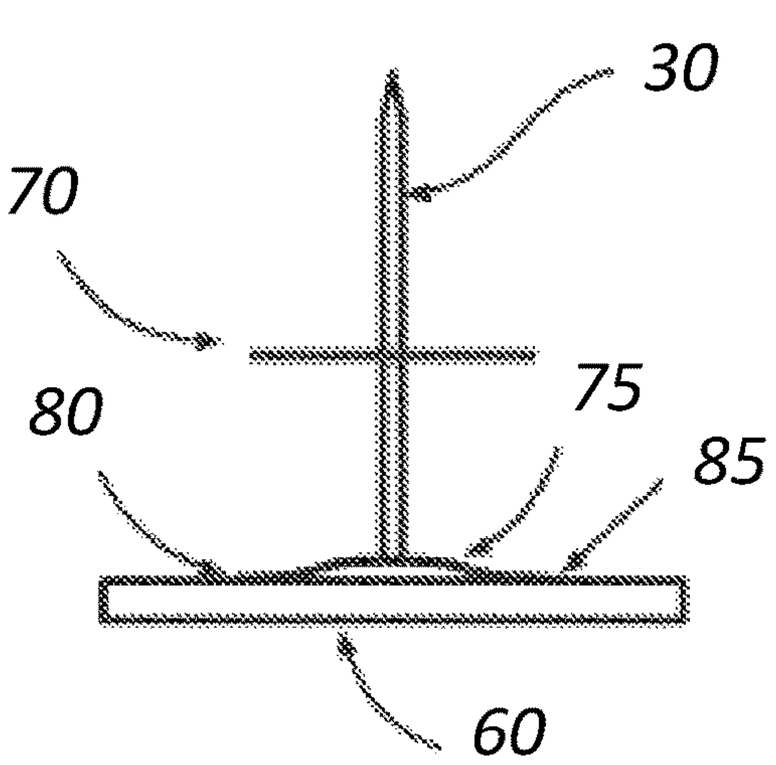


FIG. 6B

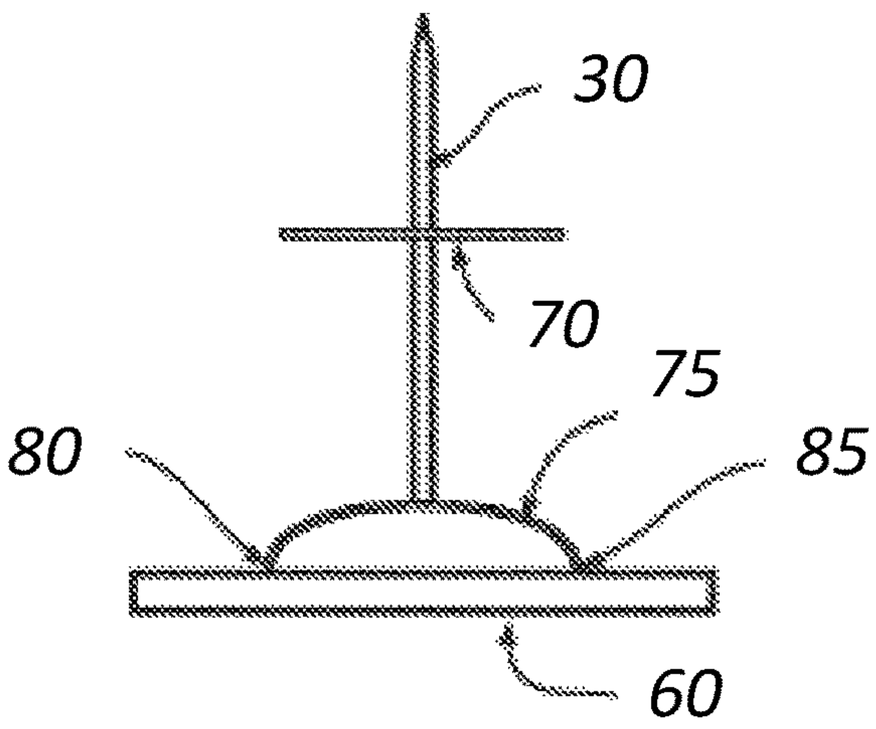


FIG. 6C

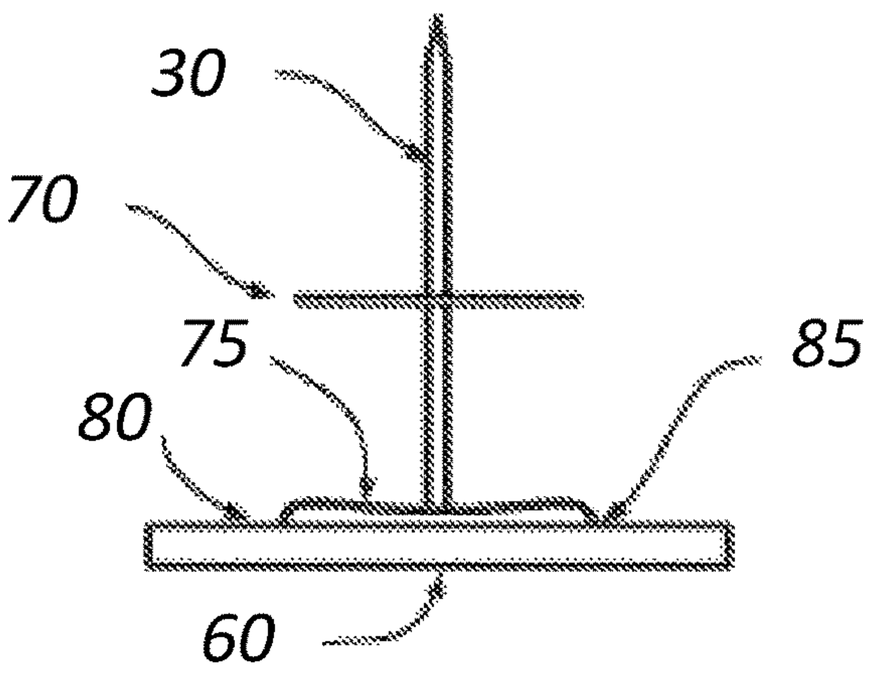


FIG. 6D

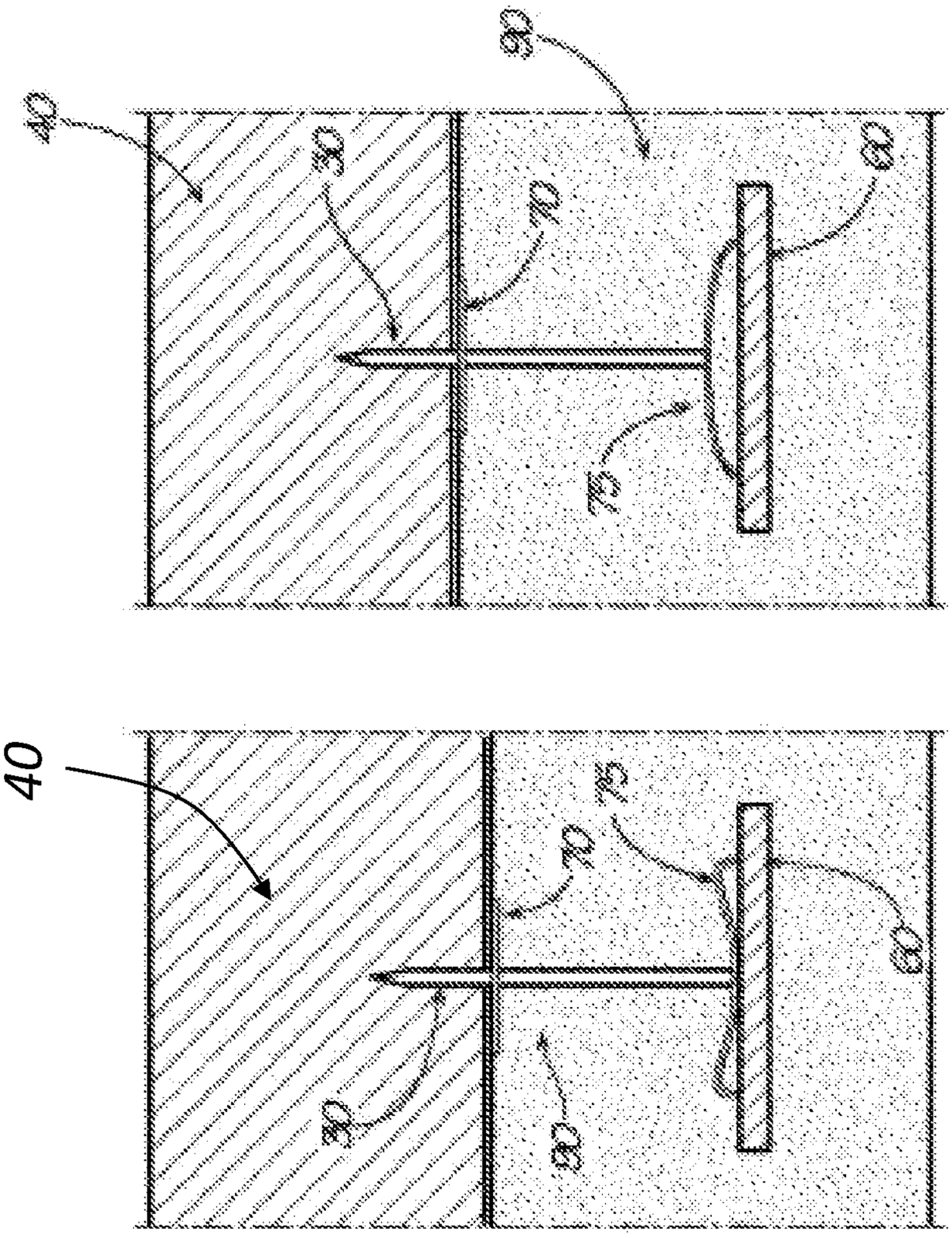


FIG. 7C

FIG. 7B

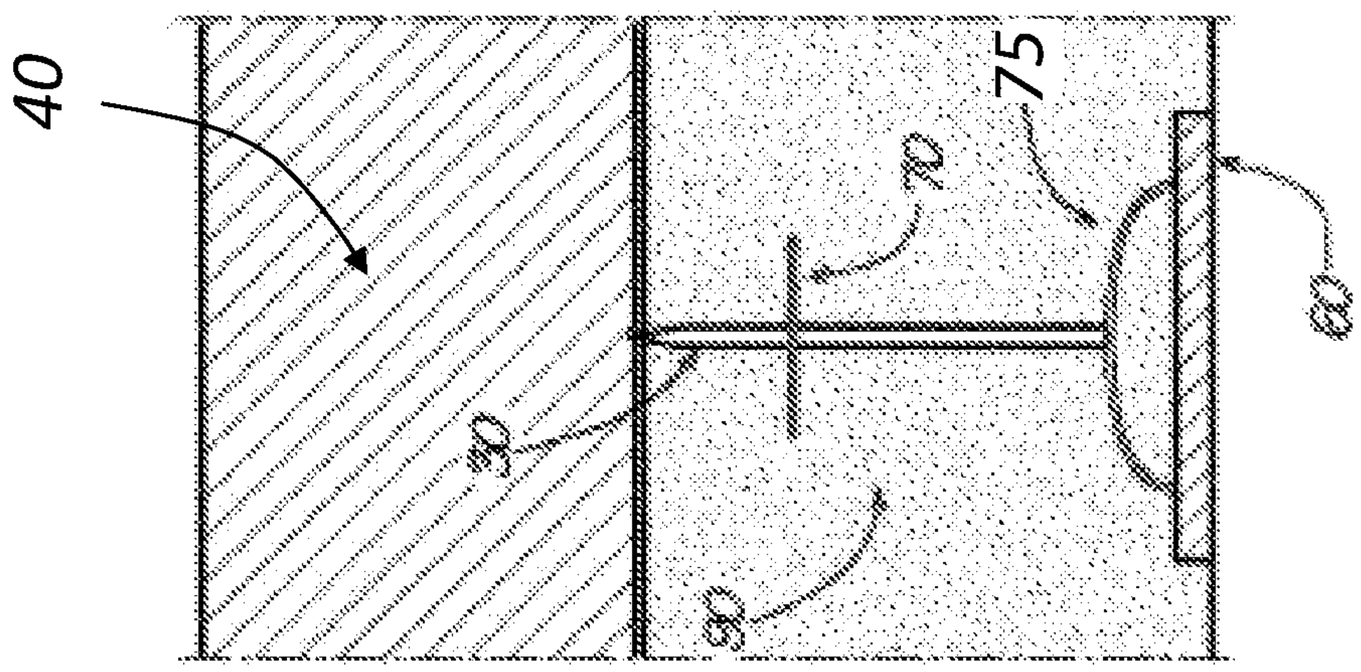


FIG. 7A

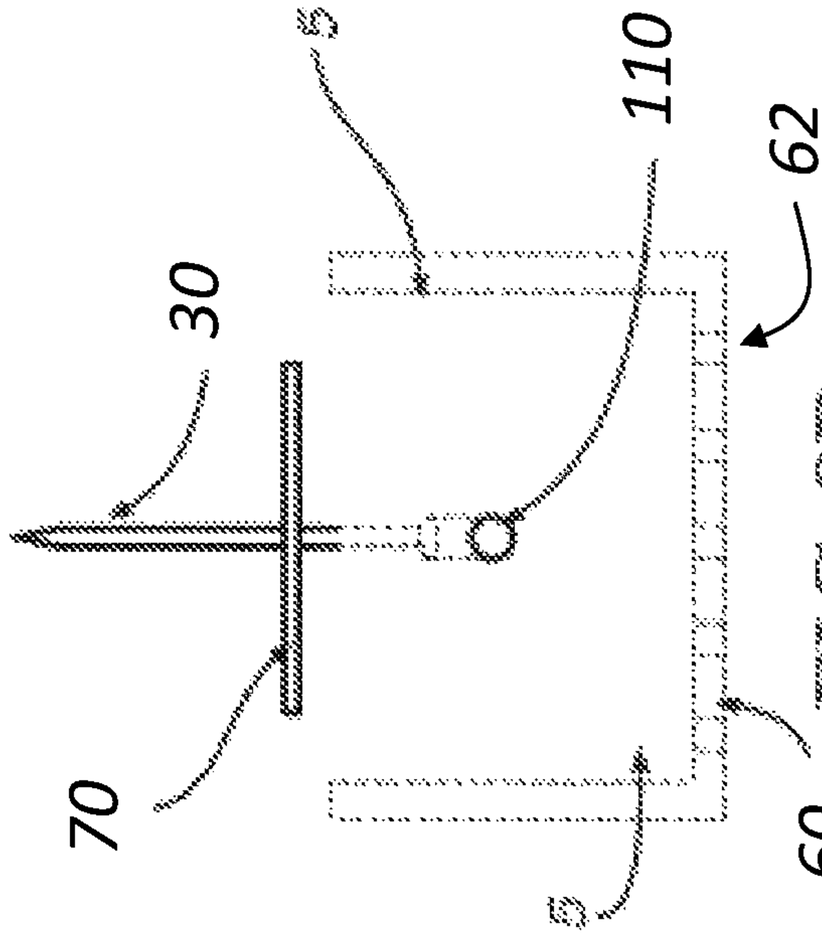
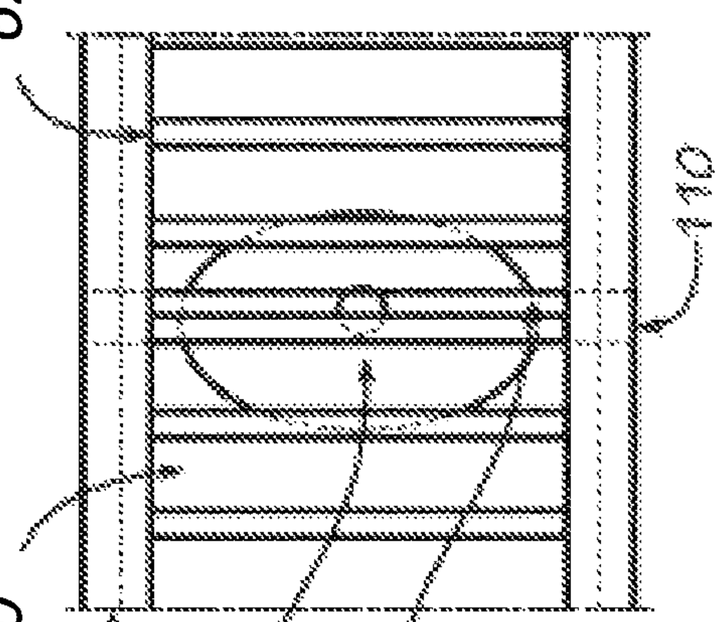


FIG. 8B



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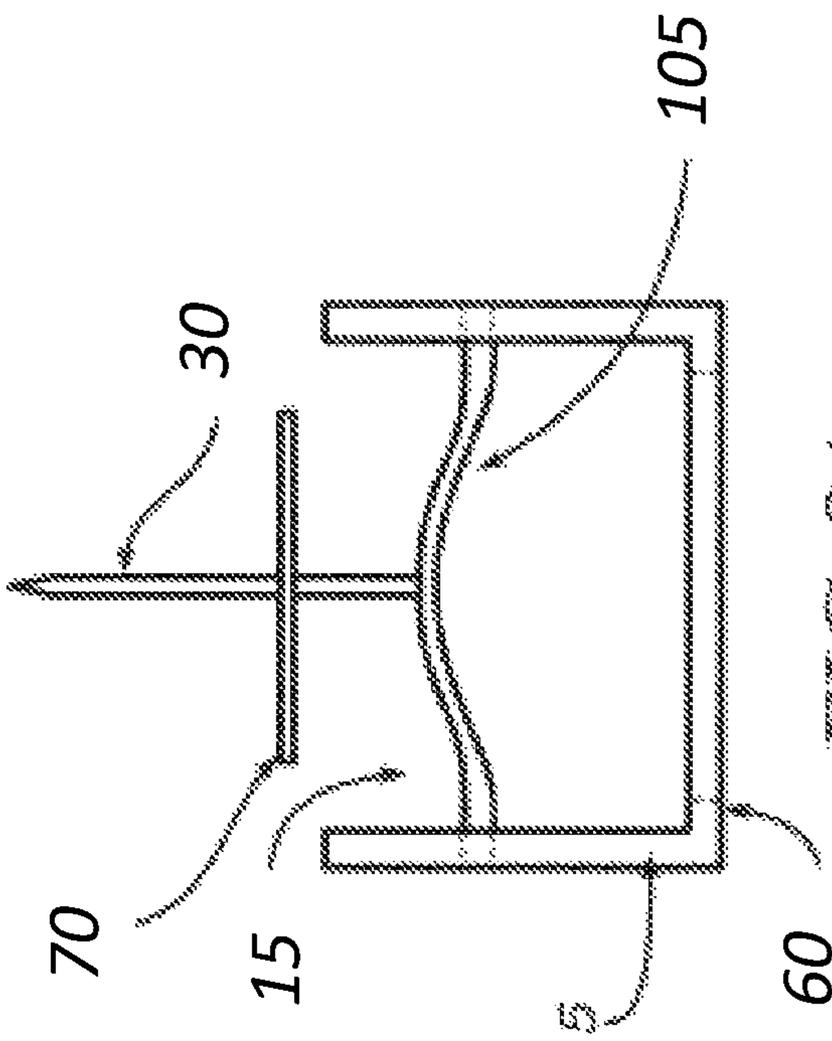

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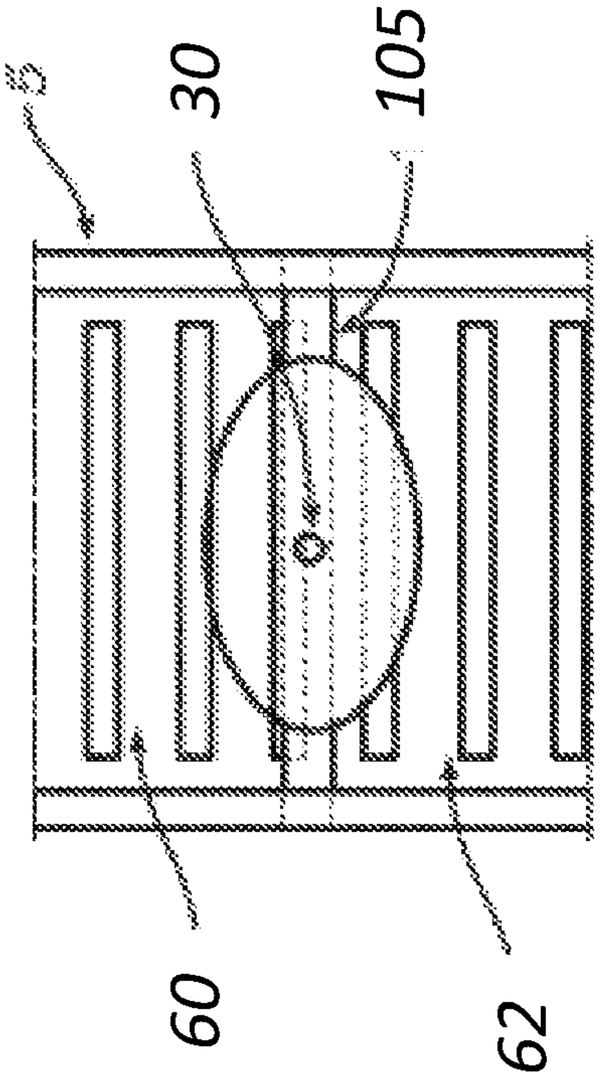

FIG. 8C

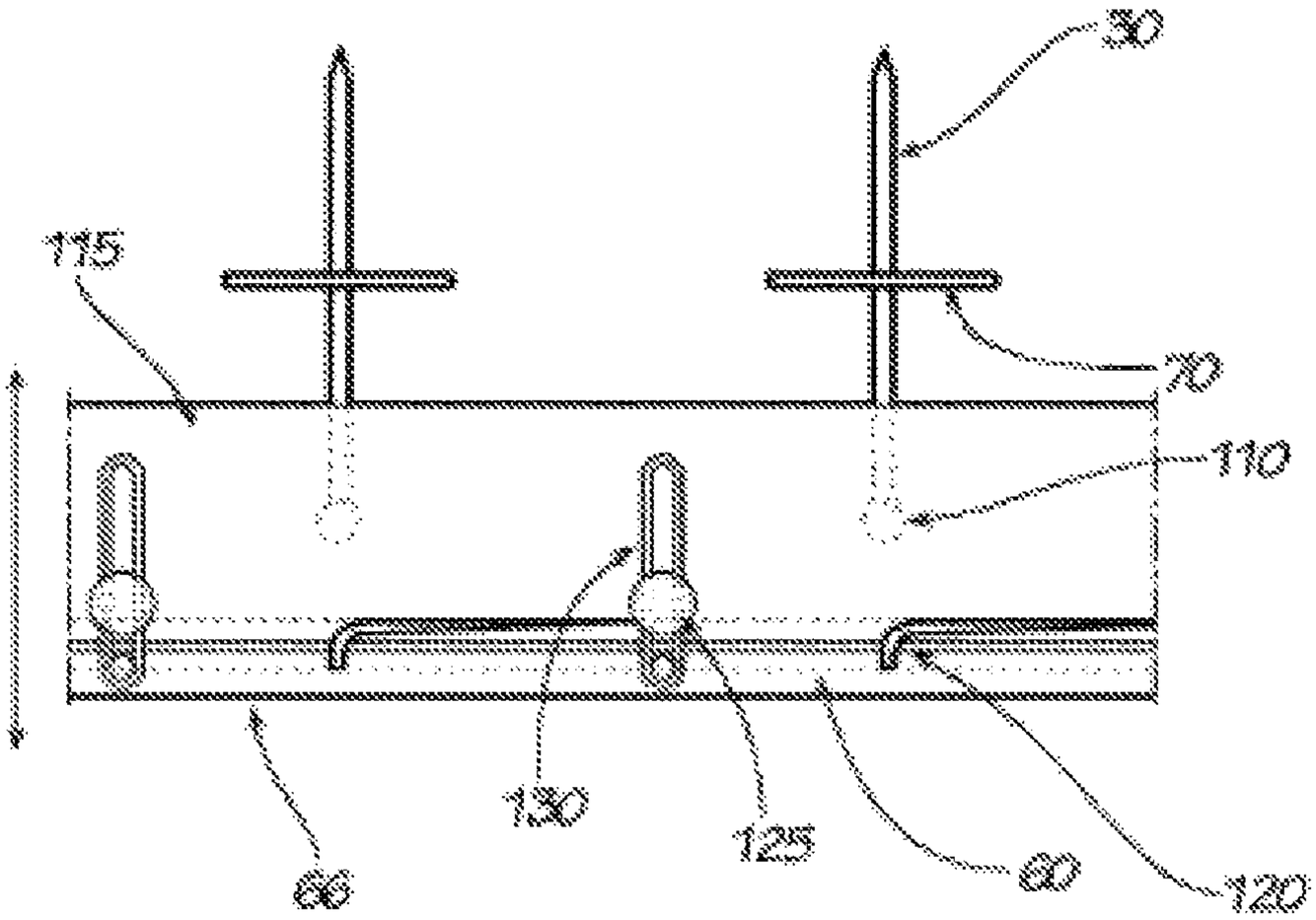

FIG. 9A

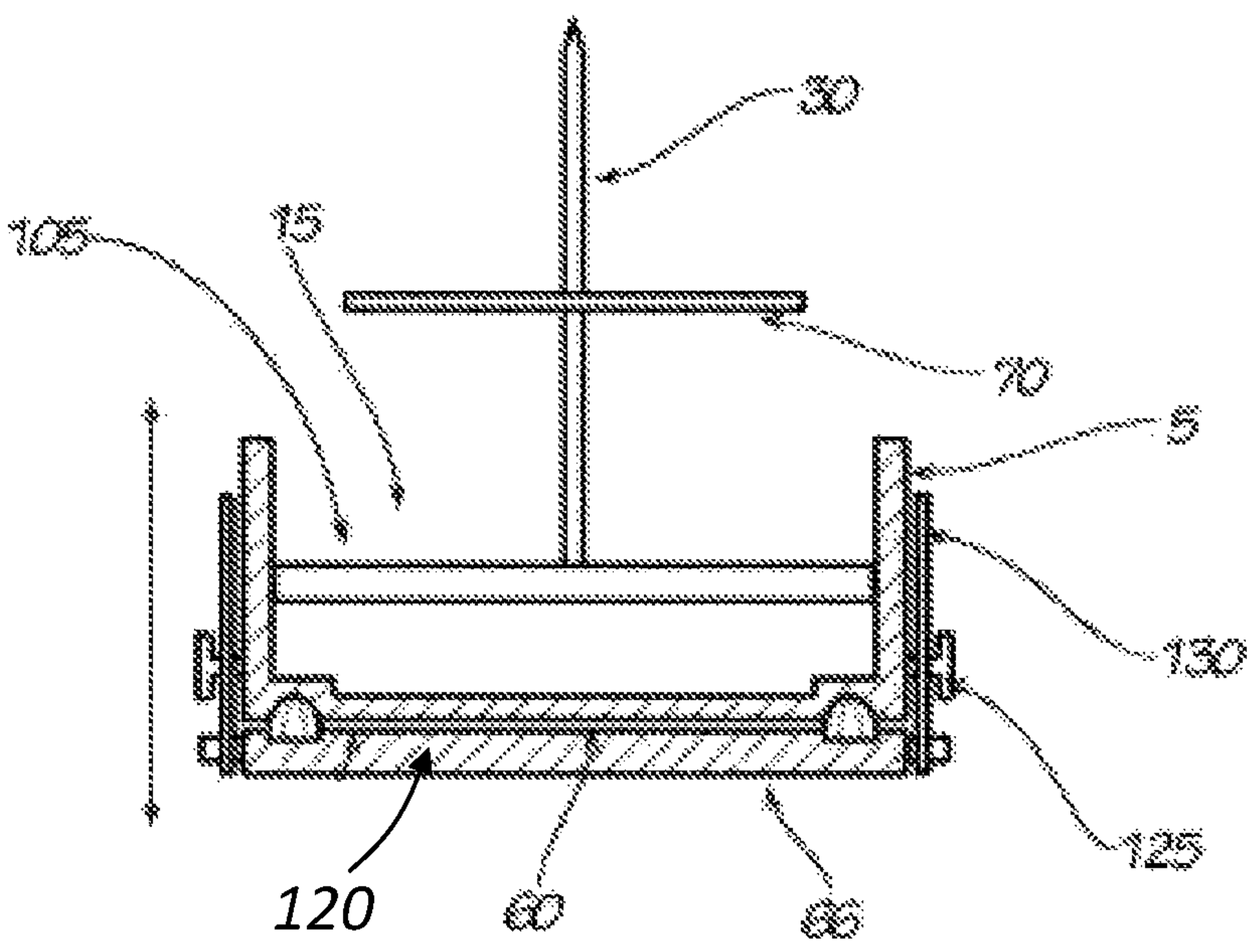

FIG. 9B

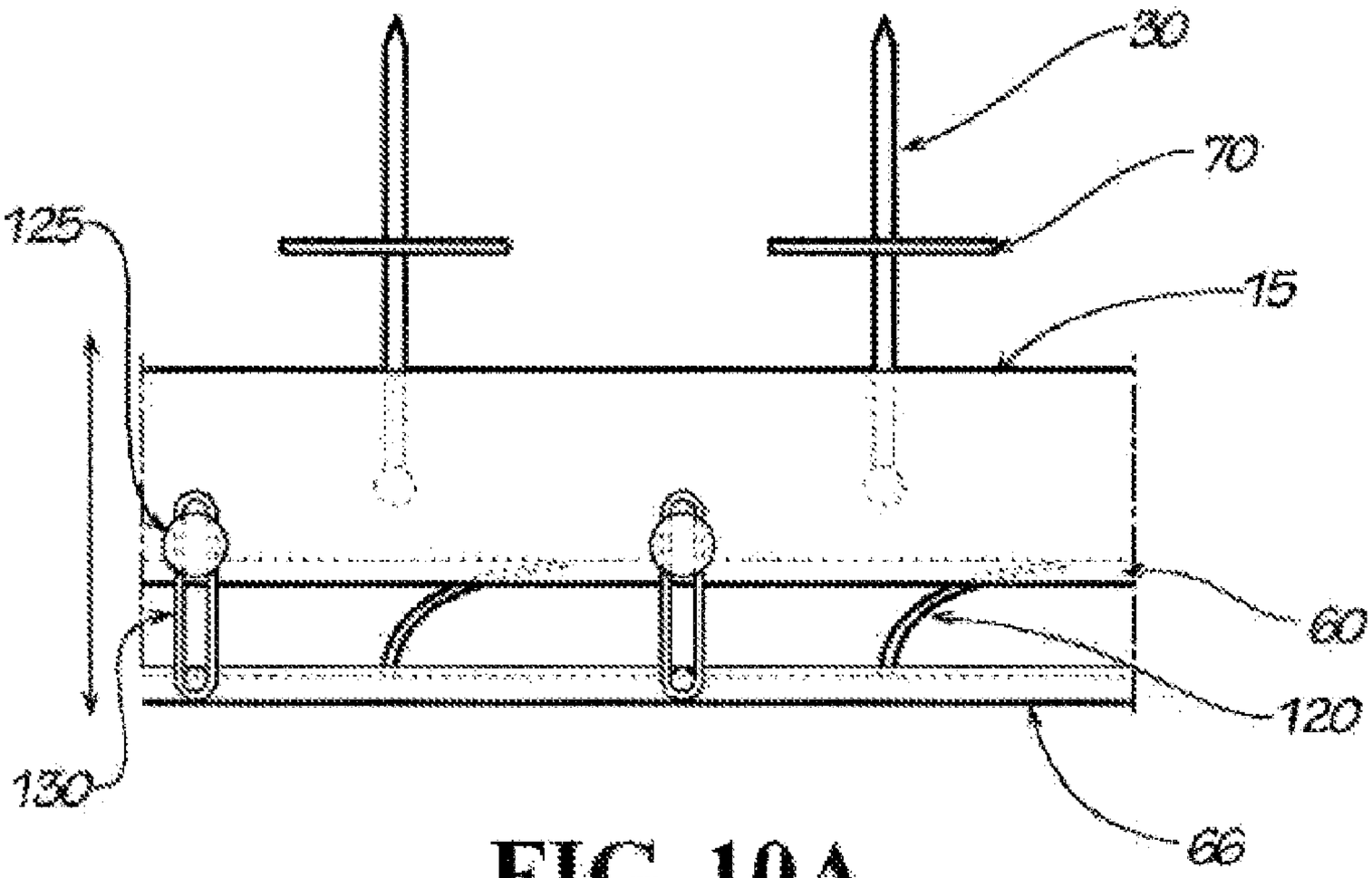

FIG. 10A

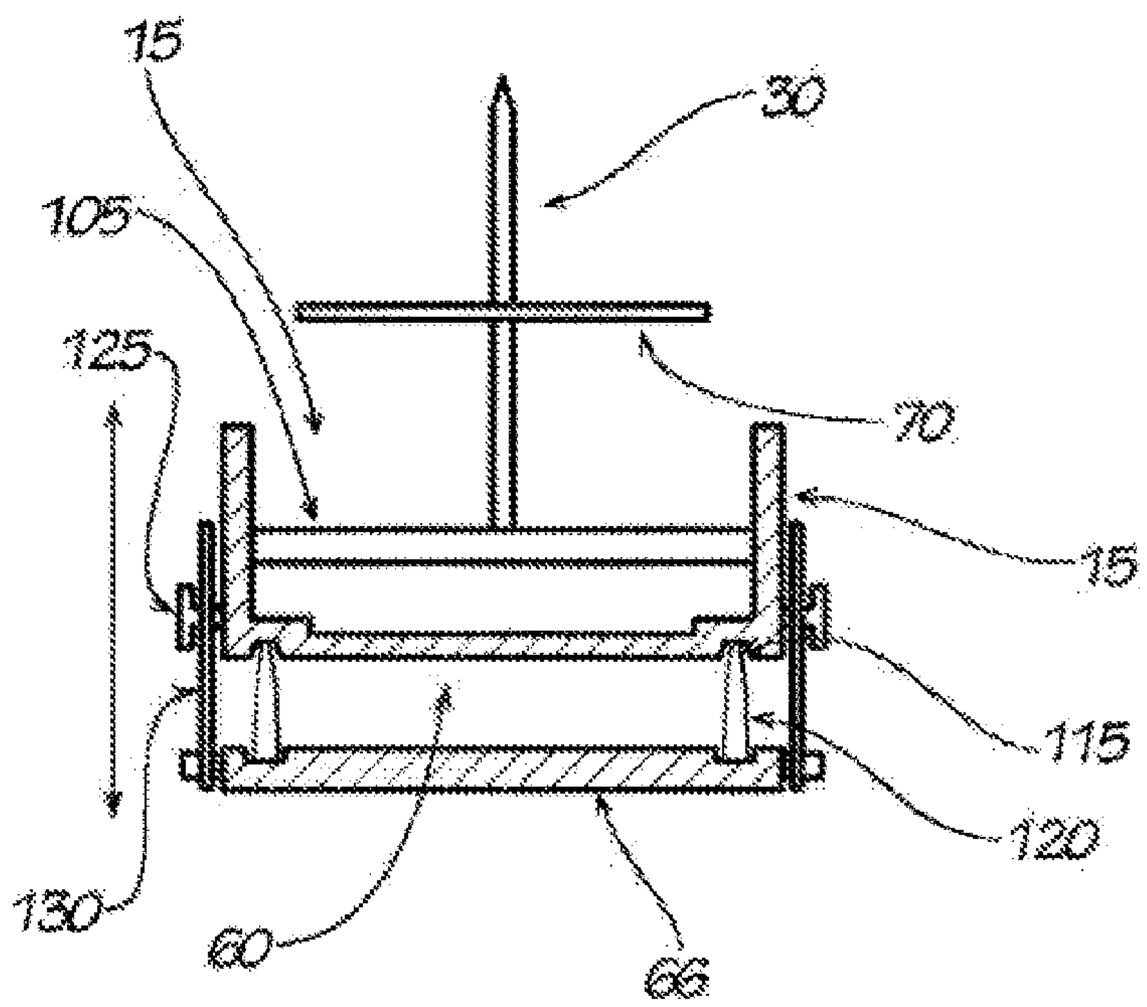

FIG. 10B

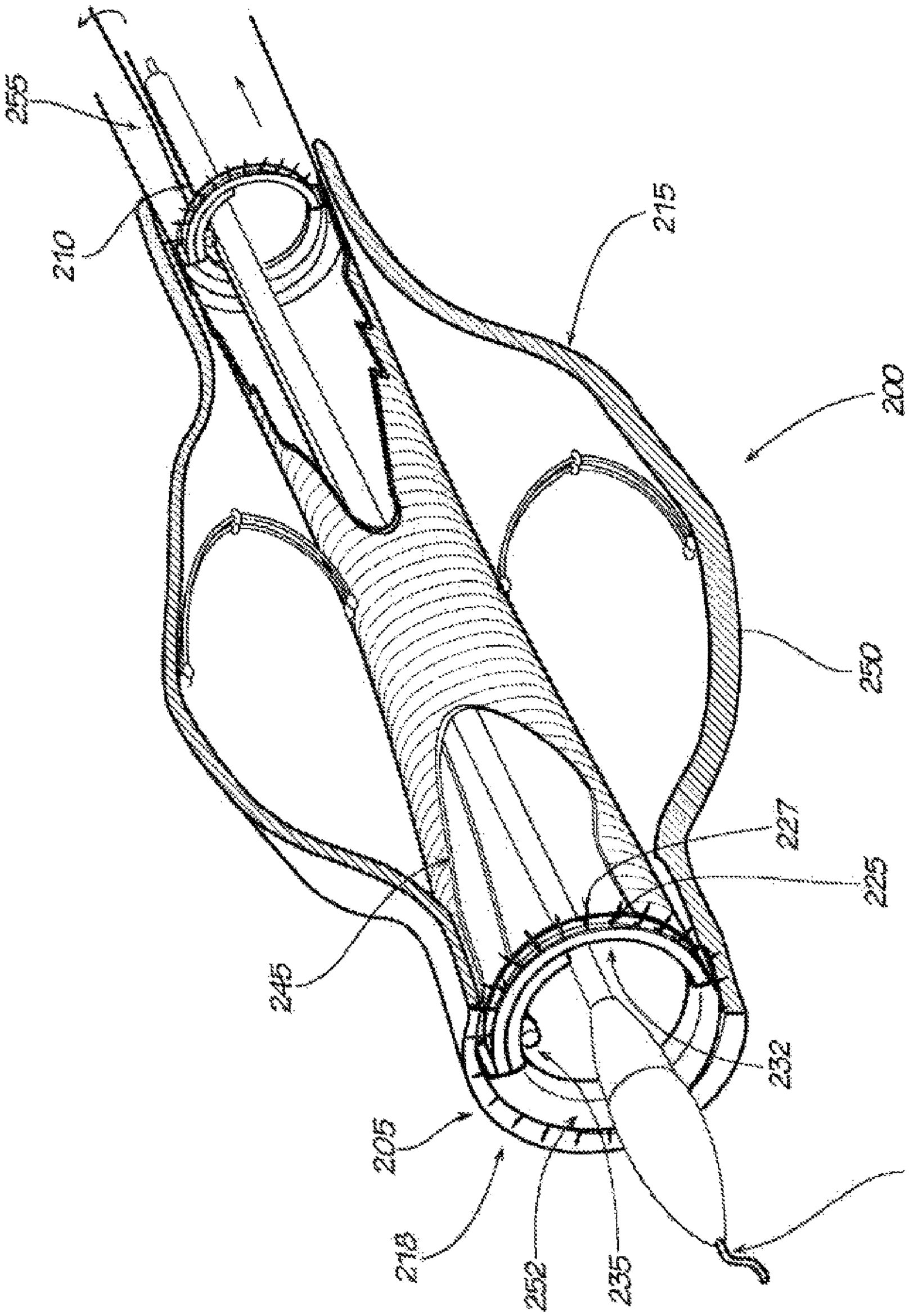

FIG. 11

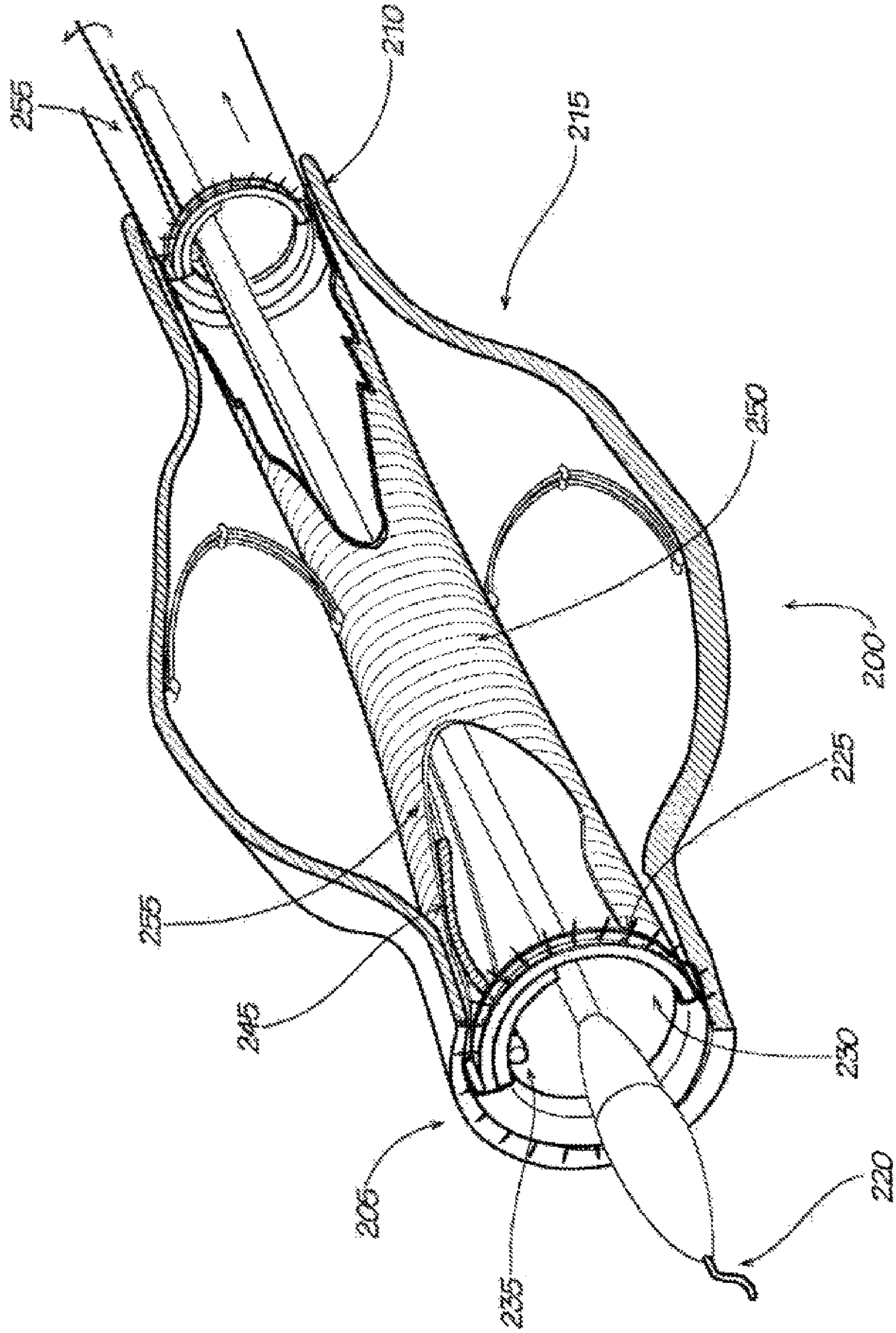

FIG. 12

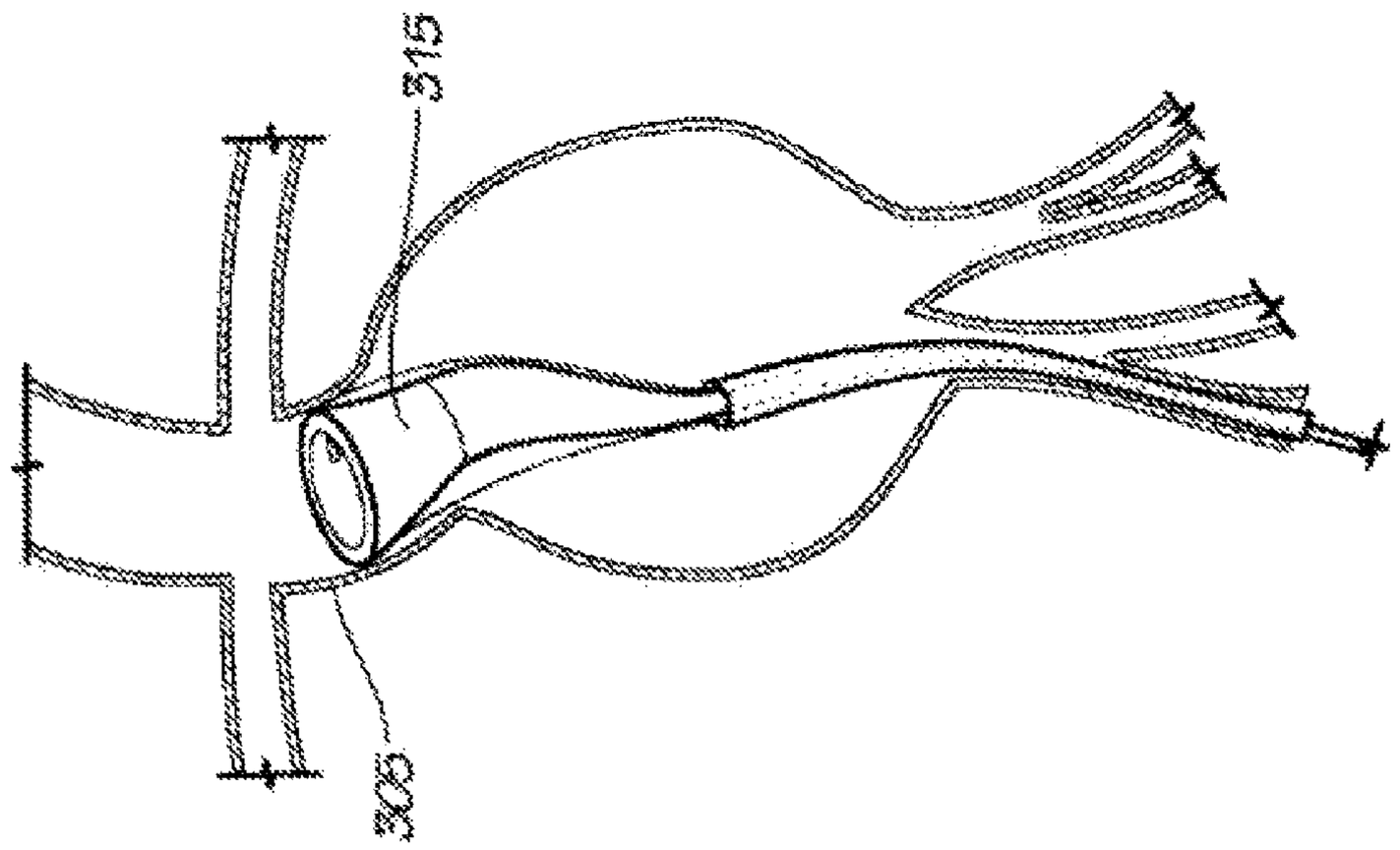

FIG. 14

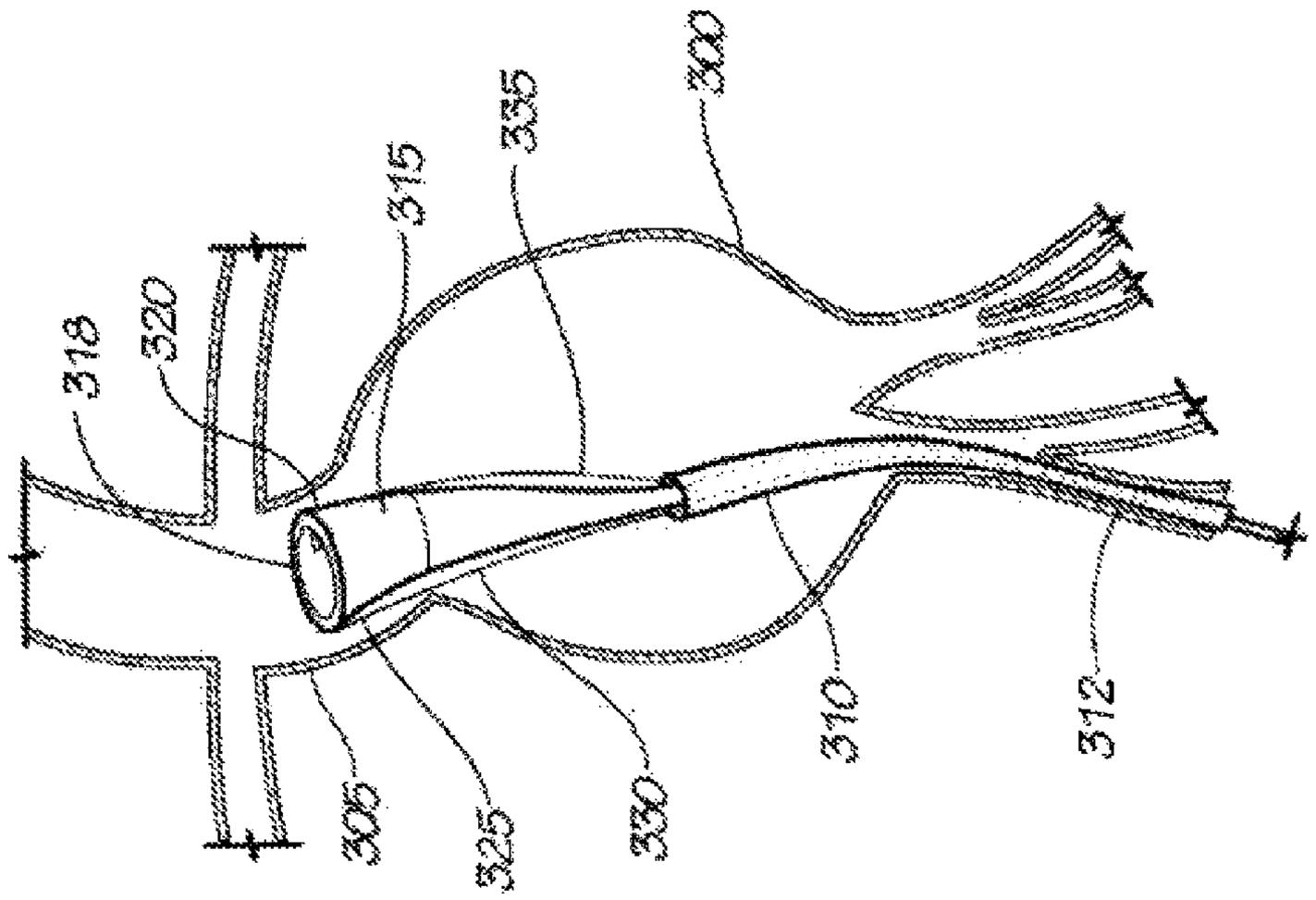

FIG. 13

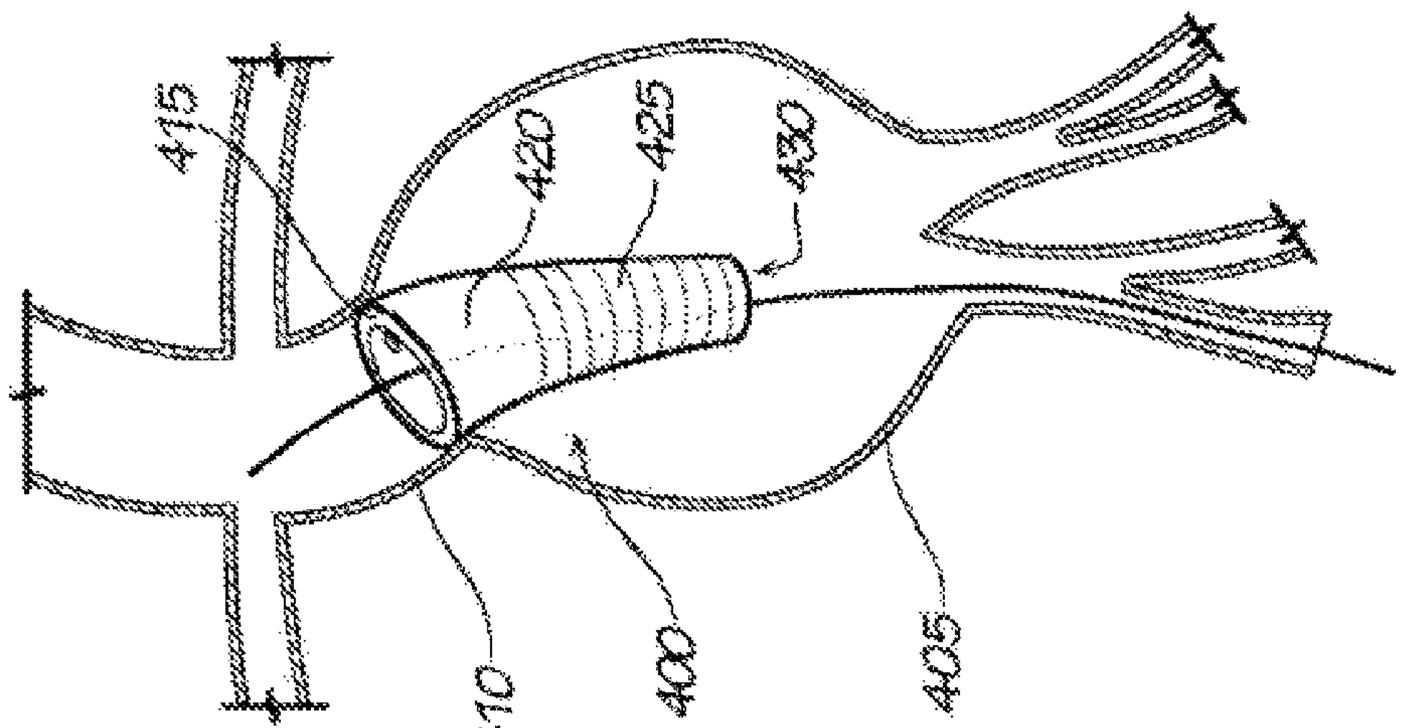

FIG. 16

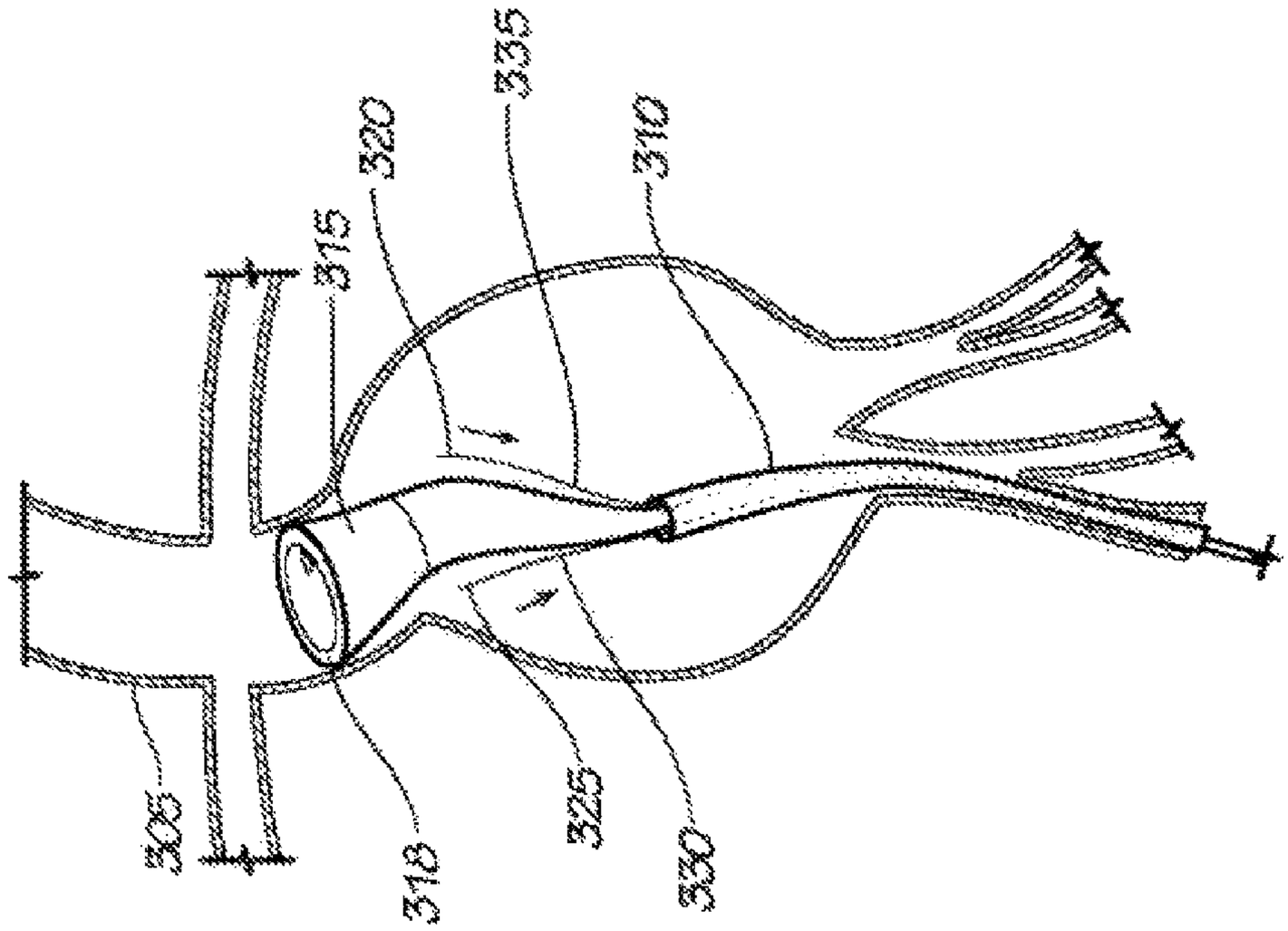

FIG. 15

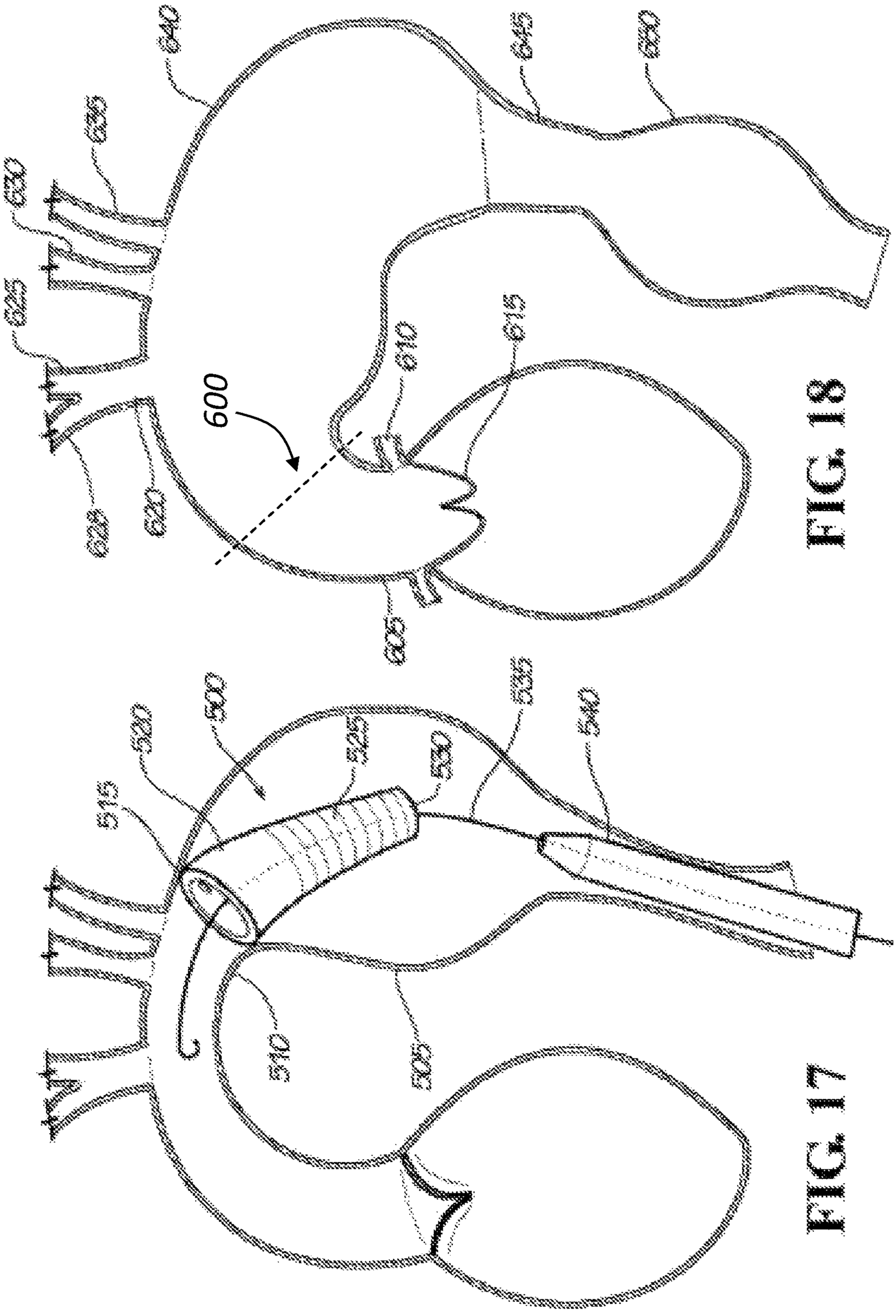

FIG. 16

FIG. 17

FIG. 18

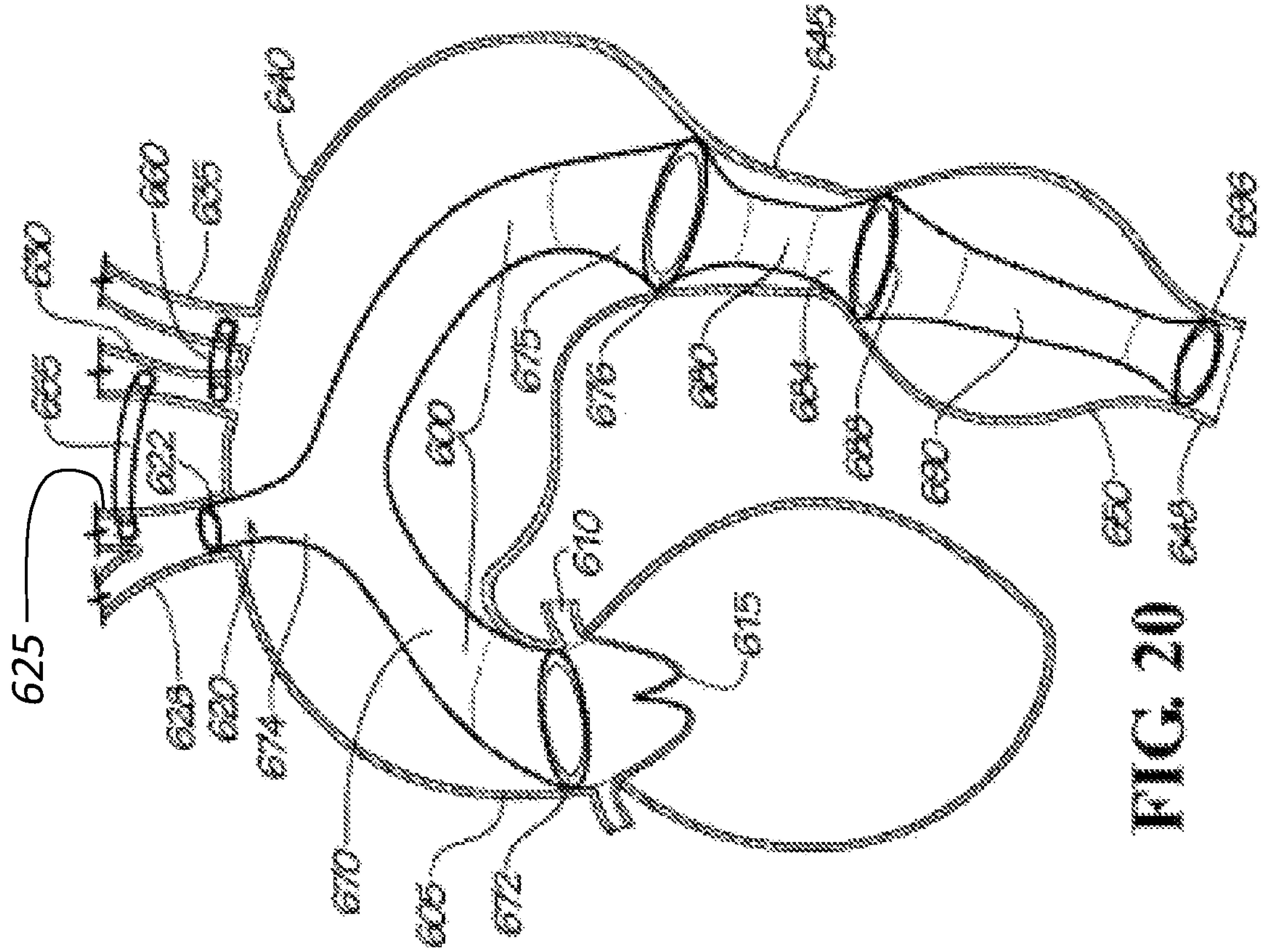
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FIG. 20

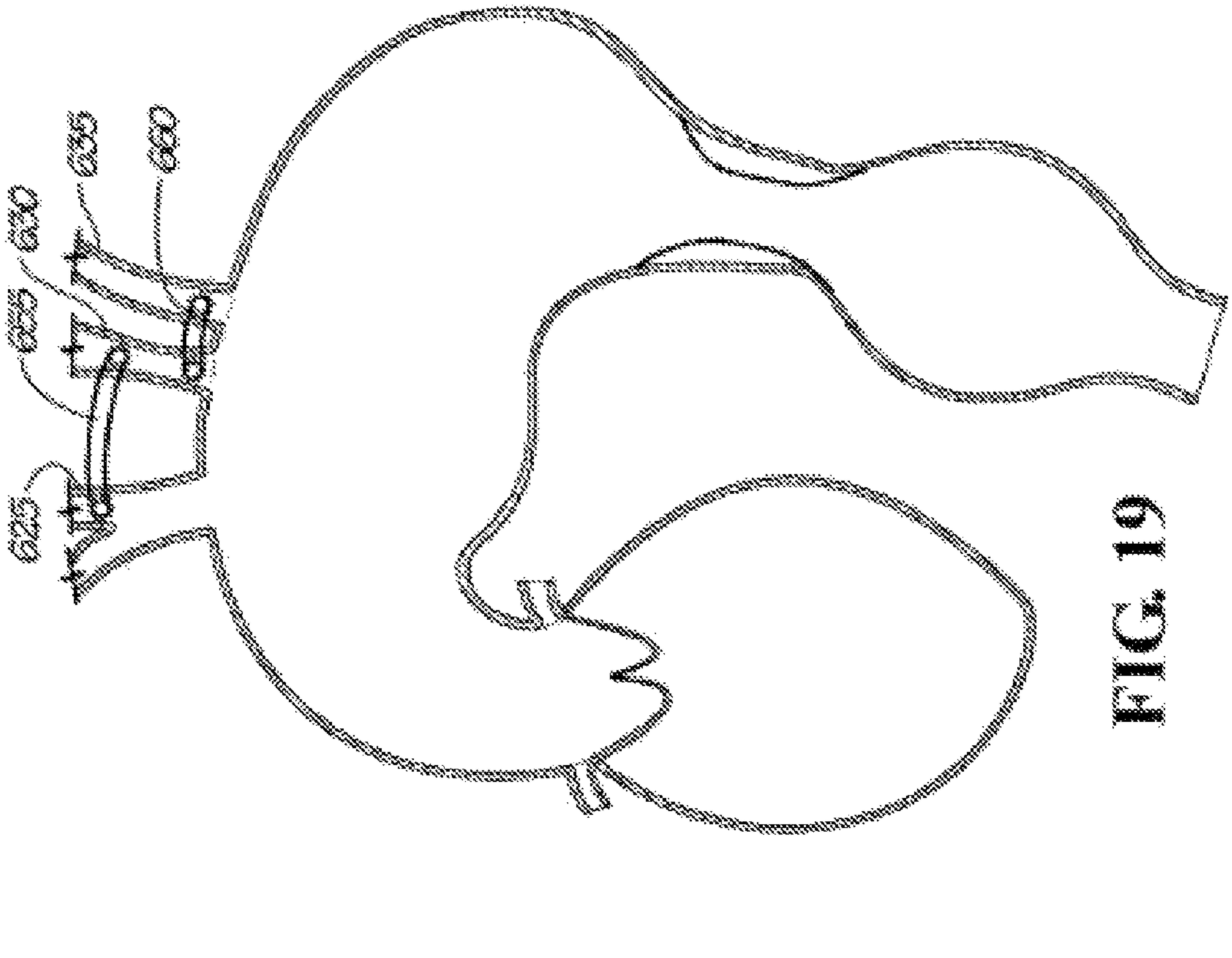
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FIG. 19

SURGICAL IMPLANT DEVICES AND METHODS FOR THEIR MANUFACTURE AND USE

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation of U.S. patent application Ser. No. 15/934,850, filed Mar. 23, 2018, which is a continuation of U.S. patent application Ser. No. 15/213,125, filed Jul. 18, 2016, now U.S. Pat. No. 9,925,033, which is a divisional of U.S. patent application Ser. No. 12/822,291, filed on Jun. 24, 2010, now U.S. Pat. No. 9,408,607, which claims the benefit of U.S. Provisional Application No. 61/222,646, filed on Jul. 2, 2009. The entire disclosures of the related applications are incorporated by reference herein.

FIELD OF THE INVENTION

The present disclosure relates to the field of surgical implant devices and method for their manufacture and use. In particular, this disclosure relates to medical devices applicable to vascular surgery and the treatment of aneurysms or other luminal defects in other anatomic conduits.

BACKGROUND OF THE INVENTION

Medical and surgical implants are often placed in anatomic spaces where it is desirable for the implant to conform to the unique anatomy of the targeted anatomic space to secure a seal therein, preferably without disturbing or distorting the unique anatomy of said targeted anatomic space.

While the lumens of most hollow anatomic spaces are ideally circular, in fact the cross-sectional configurations of most anatomic spaces are at best ovoid, and may be highly irregular. Lumenal irregularity may be due to anatomic variations and/or to pathologic conditions that may change the shape and topography of the lumen and its associated anatomic wall.

Examples of anatomic spaces where such implants may be deployed include, but are not limited to, blood vessels, the heart, other vascular structures, vascular defects, the trachea, the oropharynx, the esophagus, the stomach, the duodenum, the ileum, the jejunum, the colon, the rectum, ureters, urethras, fallopian tubes, biliary ducts, pancreatic ducts, or other anatomic structures containing a lumen used for the transport of gases, blood, or other liquids or liquid suspensions within a mammalian body.

Among vascular effects that are addressed by some preferred embodiments of the present disclosure are thoracic and abdominal aortic aneurysms.

In order for a patient to be a candidate for existing endograft methods and technologies, a proximal neck of at least 15 mm of normal aorta must exist between the origin of the most inferior renal artery and the origin of the aneurysm in the case of abdominal aneurysms or the left subclavian artery for thoracic aortic aneurysms in order to permit an adequate seal. Similarly, at least 15 mm of normal vessel must exist distal to the distal extent of the aneurysm for an adequate seal to be achieved.

Migration of existing endografts has also been a significant clinical problem, potentially causing leakage and revascularization of aneurysms and/or compromising necessary vascular supplies to arteries such as the carotid, subclavian, renal, or internal iliac vessels. This problem has been partially addressed by some existing endograft designs, in which barbs or hooks have been incorporated to help retain the endograft at its intended site. However, these existing endograft designs are not removable and repositionable once they are deployed. Thus, once such an endograft has been placed, open surgery is necessary if there is failure due to leakage or undesired occlusion of other vascular structures.

Because of the limitations imposed by existing vascular endograft devices and endovascular techniques, approximately eighty percent of abdominal and thoracic aneurysms repaired in the U.S. are still managed though open vascular surgery, instead of the lower morbidity of the endovascular approach.

SUMMARY OF THE INVENTION

Implant devices according to the present disclosure are provided with one or more improvements that increase the ability of such an implant to be precisely deployed or re-deployed, with better in situ accommodation to the local anatomy of the targeted anatomic site, and/or with the ability for post-deployment adjustment to accommodate anatomic changes that might compromise the efficacy of the implant.

One aspect of the present disclosure is directed towards novel designs for endovascular implant grafts, and methods for their use for the treatment of aortic aneurysms and other structural vascular defects. A sealable, repositionable endograft system for placement in a blood vessel is disclosed, in which an endograft implant comprises a non-elastic tubular implant body with an elastic proximal ends and an elastic distal end(s). Both the elastic proximal and distal ends in an implant according to the present disclosure further comprise one or more circumferential sealable collars and one or more variable sealing device, capable of controllably varying the expanded diameter of said collar upon deployment to achieve the desired seal between the collar and the vessel's inner wall. An endovascular implant according to the present disclosure further comprises a central lumen and one or more control leads extending distally from releasable connections with each variable sealing device. Embodiments of endovascular implants according to the present disclosure may further be provided with retractable retention tines or other retention devices allowing an implant to be repositioned before final deployment. An endograft system according to the present disclosure further comprises a delivery catheter with an operable tubular sheath, capable of housing a folded or compressed endograft implant prior to deployment and capable of retracting or otherwise opening in at least its proximal end to allow implant deployment, said sheath sized and configured to allow its placement via a peripheral arteriotomy site, and of appropriate length to allow its advancement into the thoracic or abdominal aorta, as required for a specific application.

Post-implantation remodeling of the aortic neck proximal to an endovascular graft (endograft) has been reported. While this phenomenon may be due to aortic wall injury caused by the over-dilatation (typically 110%) of the aorta to deploy the metallic lattice that supports such endografts, existing endograft technology does not allow for the management of this condition without placement of an additional endograft sleeve to cover the remodeled segment, again requiring the over-dilatation for deployment.

Endografts of the present disclosure do not require balloon over-dilatation for their deployment. Moreover, the improvements in implant design described herein allow for better accommodation by the implant of the local anatomy, as opposed to altering the local anatomy to conform to the

implant as is the presently accepted practice. Finally, implants with improvements of the present disclosure may be provided with means to change the implant configuration post-initial deployment, allowing for manual adaptation to any future anatomic remodeling at the implantation site.

The preceding description is presented only as an exemplary application of the devices and methods according to the present disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**A is a perspective view of an embodiment of an implant interface according to the present disclosure.

FIG. **1**B is a detailed view of an embodiment of an implant interface according to the present disclosure.

FIG. **2** is a detailed view of an embodiment of an implant interface with a coil spring drive gear design according to the present disclosure.

FIG. **3** is a perspective view of an embodiment of an implant interface with an uncompressed spring interposition mechanism according to the present disclosure.

FIG. **4** is a perspective view of an embodiment of an implant interface with a compressed spring-tine mechanism according to the present disclosure.

FIG. **5** is a detailed view of an embodiment of an implant interface with an electromagnetic re-docking mechanism and spring-loaded remodeling attachment members according to the present disclosure.

FIGS. **6**A-**6**D are detailed views of several exemplary embodiments of spring-loaded remodeling attachment members according to the present disclosure.

FIG. **7**A is a detailed cross sectional view of an exemplary embodiment of spring-loaded remodeling attachment member contained within an uncompressed foam gasket according to the present disclosure.

FIG. **7**B is a detailed cross sectional view of an exemplary embodiment of spring-loaded remodeling attachment member deployed into an aortic wall through a compressed foam gasket with a spring-loaded remodeling attachment at full tension according to the present disclosure.

FIG. **7**C is a detailed cross sectional view of an exemplary embodiment of spring-loaded remodeling attachment member deployed into an aortic wall through a compressed foam gasket with a spring-loaded remodeling attachment at full extension to accommodate aortic remodeling according to the present disclosure.

FIGS. **8**A-**8**D are detailed views of several alternate exemplary embodiments of spring-loaded remodeling attachment members according to the present disclosure.

FIGS. **9**A and **9**B are detailed views of another exemplary embodiment of spring-loaded remodeling attachment members according to the present disclosure, in which the band containing attachment members is mounted to a fully compressed spring-tensioned suspension.

FIGS. **10**A and **10**B are detailed views of the exemplary embodiment of spring-loaded remodeling attachment members illustrated in FIGS. **9**A and **9**B according to the present disclosure, in which the band containing attachment members is mounted to a nearly fully extended spring-tensioned suspension.

FIG. **11** is a perspective view of an embodiment of an implant interface with circumferential sealable collars and a variable sealing device with a re-docking mechanism according to the present disclosure, with the re-docking mechanism not connected to a removable re-docking control lead.

FIG. **12** is a perspective view of an embodiment of an implant interface with a circumferential sealable collars and a variable sealing device with a re-docking mechanism according to the present disclosure, with the re-docking mechanism engaged by a removable re-docking control lead.

FIG. **13** is a perspective anatomic view of an embodiment of an endograft implant according to the present disclosure in which the implant delivery mechanism is remotely steerable to allow a variable plane of delivery for implantation.

FIG. **14** is a perspective anatomic view of the embodiment of an endograft implant shown in FIG. **13** in which the implant delivery mechanism has been steered to an angular plane of delivery.

FIG. **15** is a perspective anatomic view of the embodiment of an endograft implant shown in FIG. **14** in which the implant has been sealed and delivered in a desired angular site and the steering mechanism has been disengaged from the implant and is being removed through the delivery catheter.

FIG. **16** shows a perspective anatomic view of an exemplary embodiment of an endograft implant according to the present disclosure in which the implant is a universal proximal cuff implant for treatment of an abdominal aortic aneurysm.

FIG. **17** shows a perspective anatomic view of an exemplary embodiment of an endograft implant according to the present disclosure in which the implant is a universal proximal cuff implant for treatment of a thoracic aortic aneurysm.

FIG. **18** is an anatomic drawing which shows a complex aortic arch with a first aneurysm involving the aortic arch and a second aneurysm involving the descending aorta.

FIG. **19** shows the anatomic situation of FIG. **18**, in which extra-anatomic surgical bypass has been performed with bypasses between the right and left carotid and between the left carotid and left subclavian arteries.

FIG. **20** shows the same view as FIG. **19**, with exemplary endovascular placement of three embodiments of endografts of the present disclosure to traverse the pathology and maintain vital circulation.

DETAILED DESCRIPTION OF DISCLOSED EMBODIMENTS

The present disclosure may be understood more readily by reference to the following detailed description of the preferred embodiments described herein and the examples included herein. However, before the preferred embodiments of the devices and methods according to the present disclosure are described, it is to be understood that this disclosure is not limited to the exemplary embodiments described within this disclosure, and the numerous modifications and variations therein that will be apparent to those skilled in the art remain within the scope of the disclosure provided herein. It is also to be understood that the terminology used herein is for the purpose of describing specific embodiments only and is not intended to be limiting.

Unless otherwise noted, the terms used herein are to be understood according to conventional usage by those of ordinary skill in the relevant art. In addition to the definitions of terms provided below, it is to be understood that as used in the specification and in the claims, "a" or "an" can mean one or more, depending upon the context in which it is used.

Certain aspects of the present disclosure are directed towards novel designs for sealable and repositionable endo-

vascular implant grafts, and methods for their use for the treatment of aortic aneurysms and other structural vascular defects.

In an exemplary embodiment according to the present disclosure, a sealable vascular endograft system for placement in a vascular defect is provided, comprising an elongated main implant delivery catheter with an external end and an internal end for placement in a blood vessel with internal walls. In such an exemplary embodiment, the main implant delivery catheter further comprises a main implant delivery catheter sheath which may be openable or removable at said internal end and a main implant delivery catheter lumen containing within a compressed or folded endovascular implant. Further in such an exemplary embodiment, an endovascular implant comprises a non-elastic tubular implant body with an elastic proximal end terminating in a proximal sealable circumferential collar controlled by a proximal variable sealing device which is operated by a proximal control lead that traverses said main implant delivery catheter and exits at said external end for interface by an operator, such that said proximal sealable circumferential collar may be expanded or contracted by said operator to achieve a fluid-tight seal between said proximal sealable circumferential collar and the internal walls of said blood vessel proximal to said vascular defect. Moreover, in such an exemplary embodiment, an endovascular implant further comprises a non-elastic tubular implant body with an elastic distal end terminating in a distal sealable circumferential collar controlled by a distal variable sealing device which is operated by a distal control lead that exits said main implant delivery catheter at said external end for interface by an operator, such that said distal sealable circumferential collar may be expanded or contracted by said operator to achieve a fluid-tight seal between said distal sealable circumferential collar and the internal walls of said blood vessel distal to the vascular defect.

In an alternate exemplary embodiment of the present disclosure, an endovascular implant comprises a non-elastic tubular implant body with an elastic proximal end terminating in a proximal sealable circumferential collar controlled by a proximal variable sealing device which is operated by a proximal control lead that traverses said main implant delivery catheter and exits at said external end for interface by an operator, such that said proximal sealable circumferential collar may be expanded or contracted by said operator to achieve a fluid-tight seal between said proximal sealable circumferential collar and the internal walls of said blood vessel proximal to said vascular defect. Moreover, in such an exemplary embodiment, an endovascular implant further comprises a non-elastic tubular implant body with an elastic distal end with a distal elastic circumferential collar of an expandable mesh or lattice formation that may be expanded by intralumenal balloon dilatation by said operator to achieve a fluid-tight seal between said distal elastic circumferential collar and the internal walls of said blood vessel distal to the vascular defect. In such an embodiment, particularly in the iliac arteries, the distal aspect of the endograft requires less pressure for an effective seal, and more length of arterial wall is usually available to allow an expandable mesh collar to be employed, compared with the proximal seal which often may be required to accommodate a shortened and/or angulated aortic neck.

In yet another embodiment of the present disclosure, the distal seal, particularly in the iliac arteries, may be effected using a self-expanding mesh endoskeleton or exoskeleton collar attached to the elastic distal end, provided such that the self-expanding mesh endoskeleton or exoskeleton collar is designed such that longitudinal traction on the deployed mesh causes the mesh to elongate and reduce its circumference. This would allow instrumentation to be inserted such as a hook that could adjust the distal seal location post implant deployment. Again, in such an embodiment, particularly in the iliac arteries, the distal aspect of the endograft requires less pressure for an effective seal, and more length of arterial wall is usually available to allow a self-expanding mesh endoskeleton or exoskeleton collar to be employed, compared with the proximal seal which often must accommodate a shortened and/or angulated aortic neck.

Exemplary endografts of the present disclosure comprising self-expanding mesh endoskeleton or exoskeleton collar may further comprise retention tines of any shape with or without barbs for better retention against the receiving vessel walls. Moreover, the retention tines in such endografts of the present disclosure may be provided as separate components that are affixed to the self-expanding mesh endoskeleton or exoskeleton collars, or they may be fabricated as integral components thereof.

In a further exemplary embodiment according to the present disclosure, an implant interface is provided for a sealable attachment of an implant to a wall within the lumen of a blood vessel or other anatomic conduit.

In a yet further exemplary embodiment according to the present disclosure, an implant interface is provided for a sealable attachment of an implant to a wall within the lumen of a blood vessel or other anatomic conduit, wherein the sealable attachment provides for auto-adjustment of the seal while maintaining wall attachment to accommodate post-implantation wall remodeling.

In a still further exemplary embodiment according to the present disclosure, an implant interface is provided for a sealable attachment of an implant to a wall within the lumen of a blood vessel or other anatomic conduit, wherein the sealable attachment provides for a re-docking mechanism to allow post-implantation correction of seal defects.

Yet other exemplary embodiments of endografts and endograft delivery systems according to the present disclosure have steering mechanisms that allow an operator to remotely angulate the implant as desired for difficult anatomic site requirements. Still other exemplary embodiments of endografts and endograft delivery systems according to the present disclosure serve as universal endograft cuffs, being first placed to offer their advantageous anatomic accommodation capabilities, and then serving as a recipient vessel for other endografts, including conventional endografts.

Further exemplary embodiments of endografts according to the present disclosure provide for endovascular treatment of complex anatomic vascular pathologies involving the aortic arch including aneurysms and dissecting aneurysms of the aortic arch.

Referring now in more detail to the drawings, in which like numerals indicate like elements throughout the several views, FIG. **1**A shows a proximal circumferential sealable implant interface **100** according to the present disclosure, comprising a sealer belt **60**, sealer belt channel side walls **5** provided in an overlapping loop and with a sealer belt channel **35** therewithin, a plurality of retention tines **30** and a compressive foam gasket **90** within said sealer belt channel **35**, and a sealing device housing **15**, all contained within an elastic sealable collar **10** which is shown in the embodiment of FIG. **1**A joined to and continuous with a tubular graft main body **25**.

FIG. **1**A further shows the proximal circumferential sealable implant interface **100** in place within the lumen defined by an aortic wall **40**, and with an injection dye catheter **22** traversing the sealable implant interface **100** and adjoining tubular graft main body **25**. Imbedded retention tines **30** are shown within the aortic wall **40**. Also shown in FIG. **1**A is a control lead **20** extending distally from its attachment to the sealing device housing **15** to exit through an arteriotomy site for operative control by an operator (not shown in FIG. **1**A).

In alternate embodiments of the present disclosure not shown in FIGS. **1**A-**11** herein, a circumferential sealable implant may comprise a freestanding implant which is coupled with or otherwise affixed to a tubular graft at the time of implantation.

FIG. **1**B shows a detailed view of one embodiment of a sealable implant interface according to the present disclosure. In FIG. **1**B, the sealable implant interface **100** comprises a sealer belt **60** and sealer belt channel side walls **5** provided in an overlapping loop and with a sealer belt channel **35** therewithin to contain a plurality of retention tines **30** and a compressive foam gasket [not shown in FIG. **1**B], and a sealing device housing **15**. Within said sealing device housing **15**, a sealer gear **50** is rotatably mounted to interface with sealer gear retainment slots [not shown in FIG. **1**B] located on the sealer belt **60**, such that rotation of the sealer gear **50** by operator action on an attached control lead **20** may cause movement of said sealer belt **60** with respect to said sealer gear **50**.

In the embodiment shown in FIG. **1**B, the sealer gear **50** is further provided with a spring interface **55** with said control lead **20**, such that an operator first depresses the spring interface **55** with said control lead **20** to allow rotation of the sealer gear **50** and resultant movement of the sealer belt **60**. When the spring interface **55** is not depressed, rotation of the sealer gear **50** is blocked by action of a locking member (not shown in FIG. **1**B).

FIG. **2** provides a more detailed view of an embodiment of the coil spring drive gear design of the sealer gear mechanism described in FIG. **1**B. FIG. **2** shows a sealer belt **60**, sealer belt channel side walls **5** provided in an overlapping loop and with a sealing device housing **15** and a sealer belt channel **35** with a plurality of uniformly distributed sealer gear retainment slots **62** therewithin configured to receive the teeth of a sealer gear **50**. The sealer belt channel **35** is provided to contain a plurality of retention tines **30** and a compressive foam gasket [not shown in FIG. **2**].

The sealer belt **60** as shown in FIG. **2** and in all other embodiments of the present disclosure may be fabricated of any suitably strong biocompatible material, including, but not limited to titanium, stainless steel, cobalt chromium alloys, other metals, other metal alloys, plastics, or ceramics.

FIG. **2** further illustrates an embodiment in which the retention tines **30** are pivotably mounted within said sealer belt channel **35** to permit their folding within said channel **35** within the overlapping segments of the sealer belt **60**.

The coil spring drive gear design of the sealer gear **55** is also detailed in FIG. **2**. Pressure transmitted by an operator through a control lead **20** to the central axel **21** of the sealer gear **50** first depresses the spring interface **55** within said sealer gear, allowing the sealer gear to rotate upon subsequent receipt of rotational forces applied by said user to said control lead **20**.

FIG. **3** shows a perspective view of an embodiment of an implant interface with an uncompressed spring interposition mechanism according to the present disclosure. The exemplary sealable implant interface **100** as shown in FIG. **3** resembles the embodiment of FIG. **1**B, with a sealer belt **60**, sealer belt channel side walls **5** provided in an overlapping loop and with a sealer belt channel **35** therewithin to contain a plurality of retention tines **30** and a compressive foam gasket [not shown in FIG. **1**B], and a sealing device housing **15**. Within said sealing device housing **15**, a sealer gear **50** is rotatably mounted to interface with sealer gear retainment slots [not shown in FIG. **3**] located on the sealer belt **60**, such that rotation of the sealer gear **50** by operator action on an attached control lead **20** may cause movement of said sealer belt **60** with respect to said sealer gear **50**.

In the embodiment of FIG. **3**, however, a segment of sealer belt **60** is replaced by an interposed and attached coiled spring **65** shown in a decompressed state. In use, motion imparted to the sealer gear **50** of the sealable implant interface **100** of FIG. **3** may serve to compress or decompress the spring **65**.

FIG. **4** shows the same embodiment of an implant interface as FIG. **3**, but with a compressed spring-tine mechanism. Compression of the spring **65** creates and maintains radial tension that allows such an embodiment of the present disclosure to automatically provide a fixed amount of adjustment in the event of post-implantation remodeling and dilation of the aorta or recipient blood vessel or anatomic conduit.

FIG. **5** provides a detailed view of an alternate embodiment of an implant interface with an electromagnetic redocking mechanism and spring-loaded remodeling attachment members according to the present disclosure. In FIG. **5** a detail of an implant interface comprises sealer belt **60** with side walls **5** provided in an overlapping loop and with a sealer belt channel **35** therewithin to contain a plurality of retention tines **30**, a plurality of uniformly distributed sealer gear retainment slots **62** therewithin configured to receive the teeth of a sealer gear **50**, and a compressive foam gasket [not shown in FIG. **5**], and a sealing device housing **15** containing a sealer gear **50**.

Also in FIG. **5**, a coil spring drive gear design of the sealer gear **55** is also detailed. Pressure transmitted by an operator through a control lead **20** attached to the central axel **21** of the sealer gear **50** first depresses a spring interface **55** within said sealer gear, allowing the sealer gear to rotate upon subsequent receipt of rotational forces applied by said user to said control lead **20**.

Furthermore, FIG. **5** shows one of more retention tines **30** pivotably attached to the side walls **63** of the sealer belt **60**, such that advancement or retraction of the sealer belt **60** by rotational action of the sealer gear causes said tines to either extend outwardly from said sealer belt **60** or retract within the sealer belt channel **35** when the circumference of the sealer belt **60** is made smaller. In the embodiment shown in FIG. **5**, one or more of the retention tines **30** may be further provided with a tine limiter element **70** which serves to limit the depth to which the retention tine **30** may be extended into the wall of the recipient blood vessel or other anatomic conduit.

In addition, as shown in FIG. **5**, one or more of the retention tines **30** may be attached to the sealer belt **60** with a pre-tensioned tine mounting element **75** (also called pre-tensioned spring element **75**, throughout) that serves to exert an outward radial force on its related retention tine **30** upon deployment.

FIGS. **6**A-**6**D provides detailed views of several exemplary embodiments of spring-loaded remodeling attachment members according to the present disclosure.

FIG. **6**A shows a sealer belt **60** with a retention tine **30** mounted at an erect angle thereto, said retention tine **30**

further comprising a tine limiter element **70** which serves to limit the depth to which the retention tine **30** may be extended into the wall of the recipient blood vessel or other anatomic conduit.

In FIGS. **6**A and **6**B, said retention tine **30** may be welded or otherwise affixed to a pre-tensioned tine mounting element **75** that serves to exert an outward radial force on its related retention tine **30** upon deployment. As shown in FIGS. **6**A and **6**B, the pre-tensioned tine mounting element **75** has two ends **80** and **85**. In the embodiment of the present disclosure as shown in FIGS. **6**A and **6**B, end **80** is welded or permanently affixed to the surface of the sealer band **60** (also called sealer belt **60**) and end **85** is free to slide across the surface of the sealer band **60** when longitudinal force is applied to the associated retention tine **30**.

In FIGS. **6**C and **6**D, said retention tine **30** may be welded or otherwise affixed to a pre-tensioned tine mounting element **75** that serves to exert an outward radial force on its related retention tine **30** upon deployment. As shown in FIGS. **6**C and **6**D, the pre-tensioned tine mounting element **75** has two ends **80** and **85**. In the embodiment of the present disclosure as shown in FIGS. **6**C and **6**D, both ends **80** and **85** are welded or permanently affixed to the surface of the sealer band **60**.

The pre-tensioned tine mounting elements **75** as shown in FIGS. **6**A-**6**D maintain radial tension that allows such an embodiment of the present disclosure to automatically provide a fixed amount of adjustment in the event of post-implantation remodeling and dilation of the aorta or recipient blood vessel or anatomic conduit.

FIGS. **7**A-**7**C show the relationship among the retention tines **30**, pre-tensioned spring elements **75**, compressible foam gasket **90**, and aortic wall **40** in an exemplary embodiment according to the present disclosure.

FIG. **7**A is a detailed cross sectional view of an exemplary embodiment of spring-loaded remodeling attachment member contained within an uncompressed foam gasket according to the present disclosure. In FIG. **7**A, a retention tine **30** with a tine limiter element **70** is shown attached to a sealer band **60** by a pre-tensioned spring element **75**. As shown in FIG. **7**A, the retention tine is completely covered by the foam gasket **90** in an uncompressed or pre-deployment condition.

Upon deployment, as shown in FIG. **7**B, the foam gasket **90** is compressed between the sealer band **60** and the aortic wall **40**, with penetration of the retention tine **30** into the aortic wall **40**. The extent of penetration of the retention tine **30** into the aortic wall **40** is limited by a tine limiter element **70** as shown In FIGS. **7**B and **7**C. FIG. **7**B shows the pre-tensioned spring element **75** at maximal tension.

FIG. **7**C is a detailed cross sectional view of the same exemplary embodiment as shown in FIG. **7**B, with deployment of retention tines **30** into an aortic wall **40** through a compressed foam gasket **90** with full extension of the pre-tensioned spring element **75** to accommodate aortic remodeling according to the present disclosure.

The embodiments of the retention tines as shown in the present drawings show the retention tines to be substantially straight, and at about ninety degree angles relative to the sealer band **60**. However, other embodiments on the present disclosure may comprise curved or otherwise angled retention tines, or retention tines that may be constructed of Nitinol or other shape/memory materials so that such retention tines become angled or curved upon deployment to further strengthen the attachment of said retention tines to the aortic walls or other recipient anatomic tissues. The retention tines in various embodiments of endografts of the present disclosure may be of any cross-sectional shape, and may further be terminally rounded, sharpened, tapered, or hooked,

In still further embodiments of the retention tines in endografts of the present disclosure, the retention tines may be barbed or non-barbed. Furthermore, the number of retention tines associated with a sealer band in various embodiments of the present disclosure may vary. Preferred embodiments of sealer bands or sealable circumferential collars of this disclosure comprise at least two retention tines. Moreover, the retention tines in endografts of the present disclosure may be provided as separate components that are affixed to the sealer bands or sealable circumferential collars, or they may be fabricated as integral components thereof.

FIGS. **8**A-**8**D provide detailed views of several alternate exemplary embodiments of spring-loaded remodeling attachment members according to this disclosure.

FIG. **8**A shows a cross section of an embodiment of a sealer belt with attached retention tines according to the present disclosure. In FIG. **8**A, a retention tine **30** with a tine limiter element **70** is affixed to a support element **105** which in turn is affixed to sealer belt channel side walls **5** which are connected to a sealer belt **60**. Elements may be affixed in this and other embodiments of the present disclosure by any means, including but not limited to welding, cementing, or mechanical fixation. A support element **105** in various embodiments of the present disclosure may further be inserted into and retained in bores or detents in the sealer belt channel side walls **5** (not shown in FIG. **8**A). Alternately still, in some embodiments of the present disclosure, a retention tine **30** may be cast or otherwise fabricated as a single unit with a support element **105**.

In various embodiments of the present disclosure, a sealer belt **60** and sealer belt channel side walls **5** may form a channel of angles ranging from about 10.degree. to about 170.degree.; more preferably from about 40.degree. to about 140.degree.; and most preferably about 90.degree. In other embodiments of the present disclosure, a sealer belt **60** and sealer belt channel side walls **5** may form a continuous structure which may be circular, ovoid, semi-circular, or semi-ovoid on cross section.

Also, in various embodiments of this disclosure, the support element **105** may be a rigid structure or it may be a pre-tensioned spring. Similarly, in various embodiments of the present disclosure, the retention tine **30** may be straight (as shown in FIG. **8**A) or it may be curved or helical in some or all its length. A retention tine **30** of the present disclosure may be fabricated from a shape memory material such as Nitinol or other metals, metal alloys, ceramics, plastics, or combinations thereof with shape memory characteristics to allow such a retention tine **30** to restore and maintain a desired shape upon its deployment.

FIG. **8**B shows a side view of the sealer belt with attached retention tines of FIG. **8**A. In FIG. **8**B, a retention bore **110** is shown in a sealer belt channel side wall **5** where it receives and retains the support element **105** and supports the retention tine **30** with a tine limiter element **70**. Also in FIG. **8**B, the sealer belt **60** is shown to comprise a plurality of uniformly distributed sealer gear retainment slots **62** therewithin configured to receive the teeth of a sealer gear [not shown in FIG. **8**B].

FIG. **8**C shows a top view of FIG. **8**A, with a retention tine **30** with a tine limiter element **70** affixed to a support element **105** which in turn is affixed to sealer belt channel

side walls **5** which are connected to a sealer belt **60** with a plurality of uniformly distributed sealer gear retainment slots **62**.

FIG. **8**D similarly shows a top view of the sealer belt with attached retention tines of FIG. **8**B, with a retention bore **110** shown in a sealer belt channel side wall **5** where it receives and retains the support element **105** and supports the retention tine **30** with a tine limiter element **70**. Also in FIG. **8**D, the sealer belt **60** is shown to comprise a plurality of uniformly distributed sealer gear retainment slots **62** therewithin configured to receive the teeth of a sealer gear [not shown in FIG. **8**D].

FIGS. **9**A and **9**B are detailed views of another exemplary embodiment of spring-loaded remodeling attachment members according to the present disclosure, in which the band containing attachment members is mounted to a spring-tensioned suspension. FIG. **9**A is a lateral view of the same exemplary embodiment of spring-loaded remodeling attachment shown in cross section in FIG. **9**B.

In FIGS. **9**A and **9**B, one or more retention tines **30** with tine limiter elements **70** are affixed to support elements **105** which in turn are affixed to sealer belt channel side walls **5** which are connected to a sealer belt **60**. A retention bore **110** shown in a sealer belt channel side wall **5** where it receives and retains the support element **105** and supports the retention tine **30** with a tine limiter element **70**.

In the exemplary embodiment shown in FIGS. **9**A and **9**B, Retention fasteners **125** affixed to the sealer belt channel side walls **5** are received and retained in slots in channel expansion elements **130**. The channel expansion elements **130** are permanently affixed to a sealer belt expansion base **66**, which may further be provided with a plurality of uniformly distributed sealer gear retainment slots **62** therewithin configured to receive the teeth of a sealer gear [not shown in FIG. **9**A or B]. Separating the sealer belt **60** and sealer belt expansion base **66** are one or more expansion spring elements **120** which exert a spring-loaded tension between the sealer belt **60** and sealer belt expansion base **66**. In FIGS. **9**A and **9**B, the one or more expansion spring elements **120** are shown in a compressed or non extended state, with close approximation between the sealer belt **60** and sealer belt expansion base **66**.

Retention fasteners **125** as used in the present disclosure may be screws, rivets, pins, or other fasteners, and may be affixed to the sealer belt channel side walls **5** by welding, adhesives, screw threads rivets, or other known means of attaching.

FIGS. **10**A and **10**B are detailed views of the same exemplary embodiment of spring-loaded remodeling attachment members according to the present disclosure as shown in FIGS. **9**A and **9**B, but showing the one or more expansion spring elements **120** in a decompressed or fully extended state, with near maximum separation between the sealer belt **60** and sealer belt expansion base **66**. Separation between the sealer belt **60** and sealer belt expansion base **66** is limited by the amount of distance allowed by the sliding action of the retention fasteners **125** within the slots of the channel expansion elements **130**.

In the exemplary embodiment of spring-loaded remodeling attachment members according to the present disclosure as shown in FIGS. **9**A, **9**B, **10**A, and **10**B, any enlargement in the diameter of the recipient anatomic conduit or blood vessel such as post-implantation aortic remodeling would allow the embodiment as shown to automatically accommodate the enlargement and maintain a leak proof seal using the spring tensioned suspension to the limit of the expansion capacity of that suspension.

FIG. **11** is a perspective view of an embodiment of an implant interface with a circumferential sealable collars and a variable sealing device with a re-docking mechanism according to the present disclosure, with the re-docking mechanism not connected to a removable re-docking control lead.

A re-docking mechanism is desirable, should post-implantation changes in the position or size of the implant be desired to either prevent leakages or provide a more advantageous anatomic position.

In FIG. **11**, an exemplary endovascular implant graft **200** of this disclosure is shown in an anatomic position within aortic walls **218** and traversing an aneurysm sac **215**, said graft comprising a proximal end **205** and a distal end **210**. An injection catheter **220** is shown extending through the proximal end **205** of the exemplary endovascular implant graft **200**. A tubular corrugated fabric graft **250** is joined proximally by a proximal elastic sealable collar **252**. Within the proximal elastic sealable collar **252** are contained a sealer belt **230** provided in an overlapping loop and with a sealer belt channel **225** therewithin, a plurality of retention tines **227** and a compressive foam gasket **240** within the sealer belt channel **225**, and a sealing device housing **235**. Extending distally within the lumen of the tubular corrugated fabric graft **250** is a re-dockable implant control lead **245**.

FIG. **12** is a perspective view of an embodiment of the same exemplary endovascular implant graft **200** of the present disclosure as shown in FIG. **11**, but with a removable re-docking control lead **255** engaged with the re-dockable implant control lead **245**. The re-docking control lead **255** as shown in FIG. **12** has been placed into the blood vessel through a distal arteriotomy site (not shown in FIG. **12**) by an operator who retains external operative control to allow re-docking and the desired alteration in the configuration and deployment of the endovascular implant graft **200**.

Re-docking of the re-dockable implant control lead **245** with a removable re-docking control lead **255** may be achieved by one of several mechanisms according to the present disclosure. The re-dockable implant control lead **245** may be provided with a helix, loop, or distal hook [not shown in the figures herein] that may be snared or otherwise engaged by a guide wire or by the removable re-docking control lead **255**. Alternately, magnetic and/or electromagnetic attraction may be employed between the re-dockable implant control lead **245** and the removable re-docking control lead **255** to allow their engagement in a high flow vascular environment. Alternately still, imaging technologies such as intravascular ultrasound and/or optical coherence tomography may be employed to allow an operator using basic endovascular invasive techniques to re-dock and interface with the re-dockable implant control lead **245** post-implantation.

FIGS. **13-15** show perspective anatomic views of an embodiment of an endograft implant according to the present disclosure in which the implant delivery mechanism is remotely steerable to allow a variable plane of delivery for implantation. The anatomic conditions in the aorta proximal to the desired recipient site for endograft implantation may be irregular or tortuous, ideally requiring an angled deployment of an endograft's proximal interface. Conventional endograft devices do not permit such angled deliveries.

In FIG. **13**, an exemplary abdominal aortic aneurysm **300** is shown with a narrow and angled proximal aortic neck **305**. A delivery catheter **310** is shown arising from the right iliac artery **312**. Extending partially from the delivery catheter **310** is the proximal portion of an exemplary endograft **315** of the present disclosure. As shown in FIG. **13**, the endograft

315 comprises a proximal sealable circumferential collar 318 which is connected to a first control wire lead 330 with a removable first control attachment 325 and a second control wire lead 335 with a removable second control attachment 320. Multiple types of attachments are used in various embodiments of the present disclosure to attach the first control wire leads 330 and second control wire leads 335 to the endograft 315. In a preferred embodiment, a removable first control attachment 325 and a removable second control attachment 320 are provided with a coiled tip that may be attached by screw action into the proximal sealable circumferential collar 318. In one aspect and as illustrated in FIGS. 13 and 14, the first control wire lead 330 and the second control wire lead 335 can be of such strength that one control wire lead can be pulled by the operator and the other control wire lead can be pushed by the operator, to achieve the desired angle to accommodate a proper seal.

FIG. 14 shows the endograft implant of FIG. 13 in which the endograft 315 has been steered to a desired angular plane of delivery. Thus, the control wire leads have been used to achieve and maintain a proper proximal seal angle, which is maintained while the gasket is enlarged and the seal is achieved by deploying the times.

FIG. 15 shows the endograft implant of FIG. 14 in which the proximal sealable circumferential collar 318 has been delivered to the desired angular site in the proximal aorta 305 and a seal has been accomplished according to the present disclosure by mechanical alteration of the proximal sealable circumferential collar 318 to seal against and then attach to the aortic wall 305. In FIG. 15, the tines have been deployed, and the removable first control attachment 325 and the removable second control attachment 320 are shown disengaged from the proximal sealable circumferential collar 318. Also in FIG. 15, the first control wire lead 330, the removable first control attachment 325, the second control wire lead 335, and the removable second control attachment 320 are shown being removed through the delivery catheter 310.

FIG. 16 shows a perspective anatomic view of an exemplary embodiment of an endograft implant according to this disclosure in which the implant is a universal proximal cuff endovascular implant for treatment of an abdominal aortic aneurysm. Endografts with the features shown in the various embodiments of the present disclosure have unique abilities to accommodate to anatomic variations that would preclude or compromise use of conventional endograft systems. For example, non-conducive anatomy can arise by virtue of angulation, calcific disease, thrombus, or a short neck. The universal proximal cuff implants of the present disclosure allow an operator to make use of their ability to securely seal and attach in anatomic sites where conventional endografts cannot be securely placed, and then allow a conventional endograft to securely dock with the universal proximal cuff endovascular implants distally.

In FIG. 16, a universal proximal cuff endovascular implant 400 has been placed in a narrow and angulated proximal aortic neck 410 and extends into an abdominal aortic aneurysm 405. The universal proximal cuff endovascular implant 400 comprises a proximal sealable circumferential collar 415 of the present disclosure, which is connected to an elastic proximal end 420 of a non-elastic tubular implant body 425 with a distal docking opening 430. The device of FIG. 16 has been delivered and implanted with the techniques of this disclosure, and contains a variable sealing device and attachment retention tines of this disclosure (not shown in FIG. 16). Once the device of FIG. 16 has been implanted as shown, an operator may engage and deliver any endograft including conventional endografts to the distal docking opening 430. Thus, the universal proximal cuff endovascular implant 400 provides a conduit that is suspended into, or extends into, the into an abdominal aortic aneurysm 405, that can serve as a neck conducive for docking any known endograft.

FIG. 17 shows a perspective anatomic view of an exemplary embodiment of an endograft implant according to the present disclosure in which the implant is a universal proximal cuff endovascular implant for treatment of a thoracic aortic aneurysm.

In FIG. 17, a universal proximal cuff endovascular implant 500 has been placed in a narrow and angulated proximal aortic neck 510 and extends into a descending thoracic aortic aneurysm 505. The universal proximal cuff endovascular implant 500 comprises a proximal sealable circumferential collar 515 of the present disclosure, which is connected to an elastic proximal end 520 of a non-elastic tubular implant body 525 with a distal docking opening 530. The device of FIG. 17 has been delivered and implanted with the techniques of the present disclosure, and contains a variable sealing device and attachment retention tines of the present disclosure (not shown in FIG. 16). Once the device of FIG. 17 has been implanted as shown, an operator may engage and deliver any endograft including conventional endografts to the distal docking opening 530. FIG. 17 shows such a delivery in progress, with a guide wire 535 in place, and a delivery catheter 540 containing an endograft being introduced for delivery into the distal docking opening 530.

FIGS. 18-20 show an exemplary pathologic condition with a complex aortic arch with a first aneurysm involving the aortic arch and a second aneurysm involving the descending aorta. Such a condition would not be treatable with conventional endografts. In FIG. 18, the ascending aorta 605 arises above the aortic valve 615 and gives off the coronary arteries 610. The area between the ascending aorta 605 and the descending thoracic aorta 645 is the aortic arch 600. The aortic arch 600 gives rise to the innominate artery 620 which divides into the right subclavian artery 628 and right common carotid artery 625, The aortic arch 600 further gives rise to the left common carotid artery 630 and the left subclavian artery 635. The right subclavian artery 628, right common carotid artery 625, left common carotid artery 630 and the left subclavian artery 635 are critical blood vessels to supply arterial blood to the arms, head, neck, and brain. FIG. 18 further shows a large first aneurysm 640 involving the aortic arch 600 and a second aneurysm 650 involving the descending thoracic aorta 645.

FIG. 19 shows the anatomic situation of FIG. 18, in which extra-anatomic surgical bypass has been performed with a first bypass 655 between the right common carotid artery 625 and left common carotid artery 630 and a second bypass 660 between the left common carotid artery 630 and the left subclavian artery 635.

FIG. 20 shows the same view as FIG. 19, with exemplary endovascular placement of three embodiments of endografts of the present disclosure to traverse the pathology and maintain vital circulation.

In FIG. 20, a first endograft 670 of the present disclosure has been placed through the aortic arch 600 with an attachment in the ascending aorta just distal to the coronary arteries using a first proximal sealable circumferential collar 672 of the present disclosure. The first endograft 670 as shown has an innominate branch 620 with an innominate sealable circumferential collar 622. The first endograft 670 traverses and excludes the first aneurysm 640 and terminates in a distal cuff 675 at the distal end of the aortic arch 600.

A second endograft **680** connects to the distal cuff **675** of the first endograft **670** using a second proximal sealable circumferential collar **676** of the present disclosure's design. As shown in FIG. **20**, the second endograft **680** traverses a segment of the descending aorta **645**. The second endograft **680** may be fenestrated [not shown in FIG. **20**] either in manufacture or surgically to allow collateral circulation to be maintained to the spinal and other vessels arising from that segment of the descending aorta **645**.

FIG. **20** further shows a second aneurysm **650** in the descending aorta **645**. In FIG. **20**, this is traversed and excluded by a third endograft **690** of the present disclosure, which is shown sealably attaching to the second endograft distal cuff **684** with a third proximal sealable circumferential collar **688** of the present disclosure's design. The third endograft **690** is shown attaching distally with a distal sealable circumferential collar **696** of the present disclosure's design.

Thus, in FIG. **20**, circulation is maintained to the arms, head, brain, and spine, while excluding two difficult thoracic aneurysms. This exemplary combination of endografts of the present disclosure and a relatively minor vascular procedure allows complete treatment of very difficult anatomic pathology that would be beyond the reach of conventional endovascular techniques and devices. This makes a variety of aortic arch pathologies within the scope of the devices and methods of this disclosure, including aortic arch aneurysms, dissecting aneurysms of the aortic arch, transposition of the great vessels, and other complex pathologies.

In addition to the making and use of endovascular implant grafts, other anatomic applications are also within the scope of the present disclosure. As an example, the mechanisms and principles disclosed herein may be applied to gastrointestinal disorders, where an intralumenal bypass may be desirable that may be placed using endoscopic techniques.

Crohn's disease (also known as regional) is a chronic, episodic, inflammatory bowel disease (IBD) and is generally classified as an autoimmune disease. Crohn's disease can affect any part of the gastrointestinal tract from mouth to anus; as a result, the symptoms of Crohn's disease vary among afflicted individuals. The disease is characterized by areas of inflammation with areas of normal lining between in a symptom known as skip lesions. The main gastrointestinal symptoms are abdominal pain, diarrhea (which may be bloody, though this may not be visible to the naked eye), constipation, vomiting, weight loss or weight gain. Crohn's disease typically involves the terminal ileum.

In an exemplary embodiment of a gastrointestinal aspect of the present disclosure, a tubular graft comprising proximal and distal sealable implant interfaces as disclosed herein is endoscopically placed and affixed proximally to and distally to a segment of intestine affected by Crohn's disease to divert the intestinal contents therethrough.

By providing an intraintestinal bypass for the conduit of intestinal contents though areas affected by Crohn's disease, local inflammatory response and sequelae in the affected areas are reduced.

Although the foregoing embodiments of the present disclosure have been described in some detail by way of illustration and example for purposes of clarity and understanding, it will be apparent to those skilled in the art that certain changes and modifications may be practiced within the spirit and scope of the present disclosure. Therefore, the description and examples presented herein should not be construed to limit the scope of the present disclosure.

Co-pending U.S. patent application Ser. No. 11/888,009, filed Jul. 31, 2007, is incorporated by reference herein in its entirety. Any other publications and patents mentioned in this disclosure are incorporated herein by reference in their entireties, for the purpose of describing and disclosing the constructs and methodologies described in those publications and patents, which might be used in connection with the methods of this disclosure. Any publications and patents discussed above and throughout the text are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the inventors are not entitled to antedate such disclosure by virtue of prior invention.

In any application before the United States Patent and Trademark Office, the Abstract of this application is provided for the purpose of satisfying the requirements of 37 C.F.R. § 1.72 and the purpose stated in 37 C.F.R. § 1.72(b) "to enable the United States Patent and Trademark Office and the public generally to determine quickly from a cursory inspection the nature and gist of the technical disclosure." Therefore, the Abstract of this application is not intended to be used to construe the scope of the claims or to limit the scope of the subject matter that is disclosed herein. Moreover, any headings that may be employed herein are also not intended to be used to construe the scope of the claims or to limit the scope of the subject matter that is disclosed herein. Any use of the past tense to describe an example otherwise indicated as constructive or prophetic is not intended to reflect that the constructive or prophetic example has actually been carried out.

We claim:

1. A vascular system comprising:

a delivery apparatus including a catheter and a control lead, wherein the catheter includes a lumen extending therethrough, and wherein the control lead extends through the lumen of the catheter and is configured to be manipulated by a user of the vascular system; and

an endovascular device releasably coupled to the delivery apparatus and including an implant body, a seal extending radially outwardly from the implant body and having a channel, and one or more tissue engaging elements positioned radially outward of the seal and pivotably coupled to the seal, each tissue engaging element having a connection portion coupled to a wall of the channel and defining a pivot axis and an engagement portion having a free end and a fixed end, wherein the implant body has an inflow end portion, an outflow end portion, and a central longitudinal axis extending from the inflow end portion to the outflow end portion, wherein the seal is configured to contact native vascular tissue to reduce leakage between the native vascular tissue and the implant body, wherein the tissue engaging elements pivot relative to the seal and about the respective pivot axis from a compressed state to an expanded state, wherein in the compressed state, the free ends of the tissue engaging elements pivot inwardly towards the seal and are positioned so as to disengage the native vascular tissue, and wherein in the expanded state, the free ends of the tissue engaging elements pivot outwardly away from the seal and are configured to engage the native vascular tissue, wherein the endovascular device further comprises a housing coupled to the implant body and a rotatable member disposed in the housing, wherein the rotatable member can be releasably coupled to the control lead of the delivery apparatus, wherein rotating the control lead such that the rotatable member rotates in a first direction results in radial expansion of the implant body and results in one or more of the tissue engaging

elements moving from the compressed state to the expanded state, and wherein rotating the control lead such that the rotatable member rotates in a second direction results in radial compression of the implant body.

2. The vascular system of claim **1**, wherein rotating the control lead such that the rotatable member rotates in the second direction results in one or more of the tissue engaging elements moving from the expanded state to the compressed state.

3. The vascular system of claim **1**, wherein the rotatable member is configured to rotate relative to the housing and the implant body about an axis that is radially offset relative to the central longitudinal axis of the implant body.

4. The vascular system of claim **1**, wherein the endovascular device further comprises a gear coupled to the implant body, and wherein the rotatable member is a locking member configured to selectively couple the control lead to the gear.

5. The vascular system of claim **4**, wherein the locking member is movable between an engaged position and a disengaged position, wherein in the engaged position, the locking member contacts the gear, and the locking member and the gear rotate together when the control lead is rotated by the user, wherein in the disengaged position, the locking member is spaced from the gear and the locking member rotates without rotating the gear when the control lead is rotated by the user.

6. The vascular system of claim **1**, wherein the control lead comprises a shaft configured to selectively engage the rotatable member.

7. The vascular system of claim **6**, wherein the rotatable member comprises an attachment portion configured to receive the shaft of the control lead.

8. The vascular system of claim **1**, wherein the implant body comprises metal and the seal comprises PTFE.

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